# THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc.	)
a Massachusetts Corporation	)
Plaintiff,	)
v.	) Civil No. 04-12457 PBS
Arthrex, Inc. a Delaware Corporation and	) ) )
Pearsalls Ltd. a Private Limited Company of the United Kingdom	) ) )
Defendants.	)

Mitek's Memorandum in Support of its Emergency Motion to Prevent Defendants From Presenting Witnesses at Trial Who Were Not Disclosed As Trial Witnesses During Fact or <a href="Expert Discovery"><u>Expert Discovery</u></a>

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#### I. Introduction

Plaintiff, DePuy Mitek, Inc., ("Mitek") submits this emergency motion to preclude Defendants, Arthrex, Inc. and Pearsalls Ltd. (collectively "Arthrex")<sup>1</sup> from presenting the testimony of Dr. Burkhart and Mr. Benavitz at trial. Trial on the issue of patent infringement only is scheduled for August 6, 2007. Arthrex first identified Dr. Burkhart and Mr. Benavitz as trial witnesses in its trial witness list. Mitek should not be prejudiced by Arthrex's unjustified, last-minute creation of new evidence that Mitek's experts did not consider or address. Nor should Mitek be prejudiced by having to depose witnesses during its trial preparation period. If Arthrex wanted to rely on these witnesses, it should have disclosed them during the discovery period. Certainly, Arthrex should not be presenting two new witnesses during a short, single-issue trial in which only a handful of witnesses will be presented.

Mitek respectfully requests a prompt ruling on this motion. Without immediate relief, Mitek will have to take time during the next few weeks before trial to depose these two, previously unidentified trial witnesses, and possibly prepare supplemental expert reports. It should not so burdened at a time when its preparing its case for trial.

#### II. Factual Background

A. Arthrex Did Not Identify, During Fact or Expert Discovery, Either Dr. Burkhart or Mr. Benavitz As A Witness Whose Testimony It May Rely Upon At Trial

Fact discovery extended from February 2005 until February 2006, except for some noticed depositions that had not been completed by the deadline (D.I. 22). Arthrex, Inc. and Mitek exchanged Rule 26(a)(1)(A) initial disclosures on February 8, 2005 (Exs. 1 and 2). Arthrex, Inc. did not identify either Mr. Benavitz or Dr. Burkhart in its Rule 26(a)(1)(A)

Arthrex, Inc. and Pearsalls Ltd. are jointly represented. Where there is a factual distinction, Mitek refers to them by their full name (*i.e.*, Arthrex, Inc. or Pearsalls Ltd.).

disclosures (Ex. 2) as persons that it may call as trial witnesses to support its claims or defenses. Pearsalls Ltd. was later added to the case, and it did not identify either witness as a person that it may call as a trial witness to support its claims or defenses in its November 14, 2005 Rule 26(a)(1)(A) disclosures (Ex. 3). Neither Arthrex, Inc. nor Pearsalls Ltd. ever supplemented its initial disclosures. In contrast, Mitek supplemented its initial disclosures three times (Exs. 4-6).

During discovery, Mitek asked Arthrex to identify each "person whom Arthrex expects to call at trial" (Ex. 7 at p. 15, interrogatory no. 14). Arthrex, Inc. answered with objections, and never identified any witness, much less Mr. Benavitz and Dr. Burkhart (Ex. 8). Further, Mitek's interrogatory no. 9 asked Arthrex, Inc. to identify people responsible for FiberWire's design, development, marketing, sales, and manufacturing, and Arthrex did not identify Mr. Benavitz or Dr. Burkhart as a person having any of those responsibilities (*id.*).

Expert discovery extended from March 2007 until July 2007. Arthrex submitted multiple expert reports from Dr. Mukherjee, Dr. Gitis, and Dr. Burks with evidence that is related to the issue of infringement. Arthrex did not identify either Mr. Benavitz or Dr. Burkhart as an expert witness during the expert discovery period and neither served an expert report, as is required by FED .R. CIV. P. 26(A)(3).<sup>2</sup>

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Arthrex's infringement expert, Dr. Mukherjee, referred to discussions with Mr. Benavitz in his expert report (Ex. 9 at 5, 31). Although this disclosure of Mr. Benavitz was not a disclosure that Arthrex had any intent of calling Mr. Benavitz at trial and was untimely, Dr. Mukherjee was relying on Mr. Benavitz for information that is no longer relevant in this action. Dr. Mukherjee relied on Mr. Benavitz's double hearsay comments that TigerWire's nylon yarn allegedly had a material affect on the novel and basic characteristics of the invention claimed in Mitek's U.S. Patent No. 5,314,446 (*id.*). After Mitek moved to strike Dr. Mukherjee's reliance on Mr. Benavitz's inadmissible statements, Arthrex stipulated that TigerWire's nylon does not materially affect the 446 Patent's basic and novel characteristics (D.I. 108 at 1, n. 2). Thus, Dr. Mukherjee's mentioned of Dr. Benavitz provides no basis for presenting Mr. Benavitz as a trial witness.

In summary, Arthrex did not provide any notice that it intended to call either Mr. Benavitz or Dr. Burkhart as a trial witness during discovery.

#### В. Arthrex First Identified Dr. Burkhart and Mr. Benavitz As Trial Witnesses In Its Pre-Trial Disclosures

Trial was originally scheduled for September 11, 2006 (D.I. 10). At the September 26, 2006 hearing on claims construction and summary judgment, the Court postponed the trial pending resolution of the parties' motions. In preparation for this trial, the parties had exchanged preliminary pretrial disclosures on September 25, 2006. In these pre-trial disclosures, Arthrex first identified Dr. Burkhart and Mr. Benavitz as fact witnesses that it "may call" at trial (Ex. 10). Mitek notified Arthrex of its objections to these witnesses, and attempted to resolve the issues (Ex. 11; Ex. 12), but Arthrex chose not to engage in any pre-trial matters until trial was rescheduled (Ex. 13).

At the June 19, 2007 summary judgment hearing, the Court scheduled trial on the issue of infringement, and the parties exchanged pre-trial disclosures on June 29, 2007. In its pretrial disclosures, Arthrex again identified Dr. Burkhart as a person that it "may" call (Ex. 14). But Arthrex changed Mr. Benavitz's status from "may call" to someone that it intends to call (id.). Again, Mitek immediately notified Arthrex of its objections to the introduction of new evidence at this late stage (Ex.15). As the parties could not resolve the issue, Mitek brought this motion.

#### C. Anticipated Testimony of Dr. Burkhart and Mr. Benavitz

Dr. Burkhart is an orthopedic surgeon and a third-party. It is not clear why Arthrex intends to call Dr. Burkhart. Arthrex's stated reason for calling Dr. Burkhart is to rebut its own witnesses testimony (Ex. 16 at 2). Mr. Grafton, FiberWire's alleged designer, was not deposed until March 2006, which was after expert discovery had begun (Ex. 17). Mr. Grafton explained that FiberWire solved Arthrex's suture problems because it was a braid of different yarns (id. at

46:10-47:5), which is precisely what is described in Mitek's U.S. Patent No. 5,314,446. In explaining how great his idea was — and therefore how great the 446 patent is — Mr. Grafton testified that he understood Dr. Burkhart to believe the idea to be "killer" (*id.*). Arthrex apparently now wants to call Dr. Burkhart to spin Mr. Grafton's testimony, and rebut Mr. Grafton's testimony and Dr. Brookstein's (a Mitek expert) reliance on it. Of course, Arthrex could simply call Mr. Grafton if it was not seeking to substitute witnesses at the last minute.

It is not clear why Arthrex intends to call Mr. Benavitz. Mitek asked Arthrex why it intends to call him (Ex. 15), but Arthrex declined to explain the scope of his intended testimony (Ex. 16 at 2). To the best of Mitek's knowledge, Mr. Benavitz is an Arthrex employee with either marketing or technical responsibilities. With respect to marketing issues, Arthrex produced Mr. Robert Sluss, another Arthrex employee, not Mr. Benavitz, in response to Mitek's FED. R. CIV. P. 30(b)(6) deposition notice with respect to marketing issues (Ex. 18 at 12-13; Ex. 19). Likewise, with respect to technical issues, Arthrex designated Mr. Dreyfuss, another Arthrex employee, as its Rule 30(b)(6) witness (Ex. 20 at 8-9; Ex. 21). Arthrex named both Mr. Sluss and Mr. Dreyfuss on its "may call" witness list (Ex. 14). As Arthrex has both Mr. Sluss and Mr. Dreyfuss available to it, it is not clear why Arthrex needs to now call Mr. Benavitz, other than to perhaps substitute Mr. Benavitz for these witnesses. But it any event, Arthrex does not need a new Arthrex witness on any of these issues.

# III. Under FED. R. CIV. P. 37(c)(1) Arthrex Should Be Precluded From Presenting Dr. Burkhart's and Mr. Benavitz's Testimony

FED. R. CIV. P. 37(c)(1) provides that a "party that without substantial justification fails to disclose the information required by Rule 26(a) or Rule 26(e)(1), or to amend a prior response to discovery as required by Rule 26(e)(2), is not, unless such failure is harmless, permitted to use as evidence at a trial . . . any witness or information not disclosed." As described below, Arthrex

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violated Rules 26(a), 26(e)(1) and 26(e)(2) by not timely disclosing Dr. Burkhart and Mr. Benavitz as witnesses that it may present at trial. Further, Arthrex lacks substantial justification for its untimely disclosures, and its late disclosures are not harmless. Accordingly, Arthrex should be precluding from presenting Dr. Burkhart's and Mr. Benavitz's testimony at trial. *Grajales-Romero v. American Airlines, Inc.*, 194 F.3d 288, 297 (1st Cir. 1999) (affirming exclusion of witnesses who were "not properly disclosed during discovery" by identification in interrogatory responses); *Skidgell v. Bowlby*, No. 04-cv-268-P-S, 2006 U.S Dist. LEXIS 29166, at \*4 (D. Me. May 3, 2006) (holding that witnesses not identified during discovery as trial witnesses were excluded) (Ex. 22); *see also Klonoski v. Mahlab*, 156 F.3d 255, 271 (1st Cir. 1998) (explaining that under First Circuit law "absent some unusual extenuating circumstances . . . . the appropriate sanction when a party fails to provide certain evidence to the opposing party as required by the discovery rules is preclusion of that evidence from the trial").

## A. Arthrex Violated the Disclosure Requirements of FED. R. CIV. P. 26(a)(1)(A) and 26(e)(2)

FED. R. CIV. P. 26(a)(1)(A) requires a party to provide "the name, and if known, the address and telephone number of each individual likely to have discoverable information that the disclosing party may use to support its claims or defenses." *Id.* Under FED. R. CIV. P. 33(b)(1), Arthrex had a duty to answer Mitek's interrogatories. Further, under FED. R. CIV. P. 26(e)(2), Arthrex had a duty to timely supplement both its Rule 26(a)(1)(A) disclosures and interrogatory answers. Arthrex undisputedly violated these rules. Arthrex did not identify either Dr. Burkhart or Mr. Benavitz in its Rule 26(a)(1)(A) disclosures (Ex. 2; Ex. 3) or in its response to Mitek's Interrogatory No. 14 (Ex. 8). Further, Arthrex did not supplement either its disclosures or interrogatory responses. Disclosure in either its Rule 26(a)(1)(A) disclosures or its interrogatory responses would have been sufficient, but Arthrex declined to provide notice in either fashion.

#### B. To the Extent, Arthrex Intends to Submit Expert Testimony Through These Fact Witnesses, Arthrex Violated FED. R. CIV. P. 26(a)(2)'s **Expert Witness Disclosure Requirements**

Although Arthrex has listed both Dr. Burkhart and Mr. Benavitz as "fact witnesses," Mitek is concerned that Arthrex will try to improperly introduce expert discovery through these witnesses in violation of FED. R. CIV. P. 26(a)(2). Mitek's concern that Arthrex will try to use these witnesses as experts stems from the fact that Dr. Burkhart is an orthopedic surgeon and Mr. Benavitz apparently has knowledge regarding FiberWire. Thus, Dr. Burkhart's testimony, as well as Mr. Benavitz's testimony, is likely to be technical in nature and information that should have been disclosed in an expert report, and he should not be permitted to provide technical expert testimony at this late stage. Under FED. R. CIV. P. 26(a)(2)(A), Arthrex was required to disclose these witnesses as expert witnesses during the expert discovery period if it intended to rely on them as experts. Further, under FED. R. CIV. P. 26(a)(2)(B), Arthrex was required to provide expert reports from these witnesses during the expert discovery if they are going to present expert testimony. But since Arthrex did not identify them or submit expert reports from them, it cannot submit expert testimony from these witnesses at trial.

#### C. Arthrex Has No Substantial Justification For Its Last-Minute **Disclosures**

Arthrex has no justification for failing to timely notify Mitek that it intends to present evidence from Dr. Burkhart and Mr. Benavitz. It is Mitek's understanding that Mr. Benavitz has been an Arthrex employee for several years, and Dr. Burkhart was apparently known to Arthrex before the suit was filed (Ex. 17 at 46:16-24). Thus, if Arthrex intended to rely on them, it should have notified Mitek during fact or expert discovery, so Mitek could have taken their depositions at the appropriate time and had its experts consider their testimony to the extent it is relevant. Further, Arthrex appears to improperly attempting to substitute Mr. Benavitz's

testimony for that of other witnesses, and Dr. Burkhart's for Mr. Grafton's testimony. *Grajales-Romero*, 194 F.3d at 297 (holding that a party may not substitute witnesses at trial for those disclosed during discovery). There is no legitimate reason for Arthrex's dilatory tactics.

Arthrex's purported justification for its untimely disclosures is that Mitek had notice of Mr. Benavitz and Dr. Burkhart and that they may have relevant information. But notice of the existence of a witness is simply not the same as notice that a party may present evidence from a witness at trial and no justification for Arthrex's untimeliness. For example, Dr. Burkhart is a third party. Mitek had no notice that Arthrex may present evidence from him at trial simply because his name surfaced during discovery. Likewise, just because Mr. Benavitz's name also surfaced, along with other persons too numerous to count, is not notice that Arthrex may present him, and every other person whose name appears during discovery, as a trial witness.

If Arthrex's argument notice standard were correct, then Mitek would have to depose every person identified in documents and at depositions for fear that Arthrex may call them at trial. For example, Arthrex's expert Dr. Mukherjee cites to a plethora of exhibits in his expert reports (*see*, *e.g.* Ex. 9, citing exhibits 1-29). Under Arthrex's standard, then Mitek would have to depose every person listed on those exhibits, such as patents and journal articles, to prevent the risk that Arthrex may call one of those persons at trial to rebut testimony from a Mitek expert about those patents. Further, Mitek would have to depose every other Arthrex and Pearsalls employee who had information about FiberWire for risk that Arthrex would call them. Arthrex's "notice of existence" of a witness standard is simply unmanageable and therefore not the correct legal standard.

In fact, Arthrex's argument — that notice of the existence of a witness is equivalent to notice that a party may present evidence from a witness — was rejected in *Skidgell v. Bowlby*,

2006 U.S. Dist. LEXIS 29166, at \*4. As explained in *Skidgell*, it is not Mitek's "obligation to attempt to predict or guess what witnesses" Arthrex "will introduce at trial." *Id.* Notice that a person may have relevant information simply does not satisfy Arthrex's disclosure and interrogatory response requirements. FED. R. CIV. P. 26(a)(1)(A) required Arthrex to identify witnesses that it "may use to support its claims or defenses" (*i.e.*, those it may call as a witness), not simply notice that a person may have relevant information. Likewise, because Mitek's interrogatory asked for an identification of trial witnesses (Ex. 7), FED. R. CIV. P. 26 and 33 required Arthrex to disclose not that a person existed and may have information, as Arthrex claims, but rather to disclose who it may call at trial. Thus, Arthrex's notice standard is incorrect and does not justify its failure to timely disclose witnesses that it may present at trial.

#### D. Arthrex's Disclosure Violations Are Not Harmless

Permitting Arthrex to present two new witnesses at this late date would severely prejudice Mitek. The trial is limited to the issue of infringement. Therefore, Mitek presumes that Arthrex present Dr. Burkhart and Mr. Benavitz to provide new evidence on the infringement issues. But since they were not previously disclosed, Mitek's experts did not consider their testimony in forming their opinions. They should not at the eleventh hour have to reconsider their opinions in light of the testimony of these witnesses. *Thibeault v. Square D Co.*, 960 F. 2d 239, 247 (1st Cir. 1992) (affirming exclusion of untimely disclosed expert witness because opposing party should not be burdened with discovery while preparing for trial); *Skidgell*, 2006 U.S. Dist. LEXIS 29196, at \*4 (holding that failure to disclose witnesses in accordance with discovery deadlines was not harmless because defendant's "tardiness prevented Plaintiff from... undertaking a more thorough investigation of their possible testimony").

Further, Mitek is preparing for trial, and it should not be distracted from its trial preparation with depositions of two additional fact witnesses. Mr. Benavitz's and Dr. Burkhart's

testimony may raise factual issues which will necessitate further fact discovery including other fact depositions.<sup>3</sup> For example, they may disclose other witnesses or provide information that Mitek may have to verify from other witnesses. Further, based on their testimony, Mitek may have to supplement expert reports.

Also, Mitek is prejudiced because it spent time and resources preparing its case and opted for certain expert testimony based on the evidentiary record. It should not be prejudiced with a change in the evidentiary record now at the last minute.

# E. The Parties' Agreement in the Case Management Order is No Reason For Presenting New Witnesses

Arthrex has tried to spin an agreement in the Case Management Order to provide justification for its last-minute disclosures. In the case management order, the parties agreed that, despite the limit on the number of fact depositions, a party would "produce any fact witnesses that they expect to have testify at trial for deposition" (D.I. 10 at 5-6). Mitek's understanding of that agreement was that if the parties exceeded the deposition limit and the opposing party timely identified an additional witness, the party could still depose that additional witness. Also, if a fact witness that was previously not known, but later became known, the parties could depose that witness even though fact discovery had been completed. For example, some of Arthrex's expert testing created new fact witnesses regarding the identification of the samples that Arthrex's experts tested. Mitek does not oppose Arthrex bringing those witnesses to trial, so long as Mitek has had the opportunity to depose them. But that agreement does not apply here because Arthrex was well aware of Mr. Benavitz, an Arthrex employee, and Dr. Burkhart, who allegedly discussed FiberWire with Mr. Grafton (Ex. 17 at 46:16-24) before the case was filed.

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Although Arthrex has offered Mr. Benavitz for deposition, it has not offered Dr. Burkhart for deposition.

Arthrex has taken the parties' agreement and twisted it into blanket permission for the parties to identify new witnesses on the eve of trial, so long as the witness was somehow identified during discovery, substitute new witnesses for deposed witnesses, and basically turn back the clock to fact discovery. But Arthrex's construction of the agreement should be rejected because it is contrary to Rule 26(a)(1)(A) and Rule 33. Under Arthrex's construction of the agreement, the parties would have agreed that Rule 26 and 33 do not apply. Surely, that was not the parties' agreement.

Further, under Arthrex's theory, the parties could identify entirely new fact witnesses and not bring to trial a single witness who was identified and deposed during fact discovery.

Arthrex's interpretation of the agreement should be rejected.

#### IV. Conclusion

Mitek requests that Arthrex be precluded from presenting the testimony of two witnesses whom it never identified during discovery as persons whose testimony it intended to rely upon. Arthrex's untimely disclosure is not justified and prejudices Mitek with a change in the factual record on the eve of trial. Accordingly, Mitek requests that Arthrex be precluded from presenting their testimony at trial.

Date: July 6, 2007

/s/ Erich M. Falke\_

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#### CERTIFICATE OF SERVICE

I certify that I am counsel for DePuy Mitek, Inc. and that true and correct copies of:

Mitek's Emergency Motion to Prevent Defendants From Presenting Witnesses at Trial Who Were Not Disclosed As Trial Witnesses During Fact or Expert Discovery;

Mitek's Memorandum in Support of its Emergency Motion to Prevent Defendants From Presenting Witnesses at Trial Who Were Not Disclosed As Trial Witnesses During Fact or **Expert Discovery: and** 

Depuy Mitek's Certification Of Good Faith Conference In Support Of Its Emergency Motion To Prevent Defendants From Presenting Witnesses At Trial Who Were Not Disclosed As Trial Witnesses During Fact Or Expert Discovery

were served on counsel for Defendants Arthrex, Inc. and Pearsalls Ltd. on this date via the Court's e-mail notification with the following recipients being listed as filing users for Defendants:

> Charles W. Saber Dickstein Shapiro LLP 1825 Eye Street, NW Washington, DC 20006 saberc@dicksteinshapiro.com

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Dated: July 6, 2007 \_/s/ Erich M. Falke\_\_\_

Erich M. Falke

## THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

DEPUY MITEK, INC., a Massachusetts Corporation,

04cv12457 PBS

Plaintiff,

v.

ARTHREX, INC., a Delaware Corporation,

Defendant.

### **DePuy Mitek's Initial Disclosures to Arthrex**

Pursuant to FED. R. CIV. P. 26(a)(1), DePuy Mitek, Inc. ("DePuy Mitek") makes the following Initial Disclosure to Arthrex, Inc. ("Arthrex"). This Initial Disclosure is based upon information reasonably available to DePuy Mitek at the present stage of this litigation and the issues as presently defined by the pleadings. DePuy Mitek reserves the right to supplement, revise, or otherwise amend the information contained herein.

#### I. PERSONS LIKELY TO HAVE DISCOVERABLE INFORMATION

The following list identifies those individuals presently known to DePuy Mitek who are likely to have discoverable information that DePuy Mitek may use to support its anticipated claims and defenses, unless solely for impeachment. DePuy Mitek reserves the right to supplement this list as a result of further investigation, discovery, or otherwise.

Individual	Address and Telephone, If Known	Information That the Person May Have
Arthur Taylor, Jr.	209 Loft Lane, Apt. 71, Raleigh, NC 27609 (retired and represented by Woodcock Washburn)	Inventor
Mark Steckel	Boston Scientific 24 Prime Park Way	Inventor

	Natick, MA 01760 (508) 647-5300	
Gary B. McAlister	DePuy Mitek	Technical information
Director of Research &	249 Vanderbilt Avenue	relating to suture products
Development Processes	Norwood, MA. 02062 (781) 251-2700	sold by DePuy Mitek.
Shelby Cook	DePuy Mitek	Technical information
Engineer	249 Vanderbilt Avenue	relating to suture products
	Norwood, MA. 02062	sold by DePuy Mitek.
	(781) 251-2700	
Mike McBreen	DePuy Mitek	Sales of suture products;
VP Sales & Marketing,	249 Vanderbilt Avenue	damages related financial
DePuy Mitek.	Norwood, MA. 02062	information.
	(781) 251-2700	
Meghan Scanlon,	DePuy Mitek	Market for suture products;
Director - Platform	249 Vanderbilt Avenue	marketing of suture
Development	Norwood, MA. 02062	products; and damages
Shoulder & Extremities	(781) 251-2700	related issues.
Matthew Goodwin, Esq.	Johnson & Johnson Law	Prosecution of the Hunter
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	Department	Patent.
	Ethicon, Inc.	

#### II. A DESCRIPTION BY CATEGORY AND LOCATION OF ALL DOCUMENTS, DATA COMPILATIONS, AND TANGIBLE THINGS THAT ARE IN THE POSSESSION, CUSTODY, OR CONTROL OF DEPUY MITEK AND THAT DEPUY MITEK MAY USE TO SUPPORT ITS CLAIMS OR DEFENSES

DePuy Mitek identifies the following categories of documents in accordance with FED. R. CIV. P. 26(a)(1)(B).

DePuy Mitek has within its possession, custody, and control documents, data compilations, and/or other tangible things falling under the general categories listed below. These may include documents subject to the attorney-client and/or work product privilege. The disclosure herein is made without a waiver of these privileges.

- Documents relating to U.S. Patent No. 5,314,446 and its prosecution history.
- Documents relating to the development of the claimed subject matter.
- Documents relating to DePuy Mitek's suture products that compete with the FiberWire<sup>TM</sup> products.
- Documents relating to Arthrex's suture products, including those incorporating FiberWire<sup>TM</sup>.
- Documents relating to the damages suffered by DePuy Mitek as a result of Arthrex's infringement.

DePuy Mitek reserves the right to supplement its initial disclosure and any production at such time as additional information comes to its attention as a result of further investigation, discovery, or otherwise. DePuy Mitek proposes that the parties agree to a mutually convenient date for exchanging initial disclosure documents.

### III. COMPUTATION OF DAMAGES

DePuy Mitek will seek damages as permitted by 35 U.S.C. §284 resulting from Arthrex's infringement of the 446 Patent, including lost profits and/or a reasonable royalty. DePuy Mitek also will seek increased damages and attorneys' fees as a result of Arthrex's willful infringement. DePuy Mitek is not able to provide any calculation of such damages at this time because necessary facts are within Arthrex's control. As set forth in the Advisory Committee notes to Rule 26(a)(1): "a party would not be expected to provide a calculation of damages which, as in many patent infringement actions, depends on information in the possession of another party or person."

#### IV. INSURANCE OR INDEMNITY AGREEMENTS

DePuy Mitek is not presently aware of any insurance agreement under which any person carrying on an insurance business may be liable to satisfy part or all of a judgment that may be entered in this action or to indemnify or reimburse for payments made to satisfy the judgment.

DEPUY MITEK, INC.,

By its attorneys,

Daniel J. Gleason (BBO #194900)

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Dated: February 8, 2005

#### **CERTIFICATE OF SERVICE**

I certify that the foregoing DePuy Mitek's Initial Disclosures to Arthrex was served by facsimile and first class mail on the following on February 8, 2005:

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Christopher Weld, Jr. Todd & Weld LLP 28 State Street, 31<sup>st</sup> Floor Boston, MA 02109 Fax: (617) 227-5777

Dated: February 8, 2005

Erich M Falke

#### Confirmation Report - Memory Send

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DATE: February 8, 2005

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Company/Firm: Dickstein Shapiro Morin & Oshinsky LLP

Telecopier No.: 202-887-0689

Client/Matter No.: DePuy Mitek Inc. v. Arthrex, Inc. Our Reference No.: JJDM-L2

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INTELLECTUAL PROPERTY LAW

# **FACSIMILE**

DATE: February 8, 2005

Please deliver this and the following pages to:

Name: Charles W. Saber

Company/Firm: Dickstein Shapiro Morin & Oshinsky LLP

Telecopier No.: 202-887-0689

Client/Matter No.: DePuy Mitek Inc. v. Arthrex, Inc.

Our Reference No.: JJDM-L2

Sender's Name: Erich M. Falke

Pages to Follow:

If transmission is not complete, please call our Philadelphia Office at (215) 568-3100.

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### IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

		·
DePuy M	litek, Inc.	
	Plaintiff,	
vs.	; 	) Case No. 04-12457 PBS
Arthrex,	Inc.,	}
	Defendant.	) )

#### **DEFENDANT ARTHREX, INC.'S INITIAL DISCLOSURES**

Pursuant to Rule 26(a)(1) of the Federal Rules of Civil Procedure, Defendant Arthrex, Inc. ("Arthrex"), by and through its counsel, makes the following disclosures. Arthrex reserves the right to supplement, amend or otherwise revise the information contained herein upon further investigation, the receipt of additional information during discovery and the course of these proceedings.

Individuals Likely to Have Discoverable Information That Arthrex May Use to Support Its Claims or Defenses

Pursuant to Rule 26(a)(1)(A), Arthrex notifies DePuy Mitek, Inc. ("DePuy Mitek") that the following individuals at this time are likely to have discoverable information that Arthrex may use to support its claims or defenses:

Reinhold Schmieding, President and Founder, Arthrex, Inc., 1370 (1)Creekside Boulevard, Naples, Florida 34108, (800) 933-7001. Mr. Schmieding is familiar with the development, marketing and sales of Arthrex's FiberWire™ surgical suture products and decisions about offering those products into the market. Further, Mr. Schmieding is familiar with the state of the art for surgical suture products.

DSMDB.1879137.1

- (3) D. Lawson Lyon, Little Burrow Farm, Broadclyst, Exeter, Devon, EXS 3JA, United Kingdom, is familiar with the development and manufacturing of Arthrex's FiberWire<sup>TM</sup> surgical suture products.
- (4) Brian Hallet, 64, Priorswood Road, Taunton, Somerset, TA2 7PT, United Kingdom, is familiar with the development and manufacturing of Arthrex's FiberWire surgical suture products.
- (5) Alastair W. Hunter, Bridgewater, New Jersey, is likely to have discoverable information relating to U.S. Patent No. 5,314,446 ("the '446 patent") and to inequitable conduct alleged to have been committed before the U.S. Patent and Trademark Office during prosecution of the '446 patent.
- (6) Arthur Taylor, Jr., Plainfield, New Jersey, is likely to have discoverable information relating to the '446 patent and to inequitable conduct alleged to have been committed before the U.S. Patent and Trademark Office during prosecution of the '446 patent.
- (7) Mark Steckel, Maineville, Ohio, is likely to have discoverable information relating to the '446 patent and to inequitable conduct alleged to have been committed before the U.S. Patent and Trademark Office during prosecution of the '446 patent.

- (8) Attorneys for Ethicon, Inc. ("Ethicon") and others on behalf of Ethicon who were involved in the prosecution of the '446 patent are likely to have discoverable information relating to the prosecution of the '446 patent and to inequitable conduct alleged to have been committed before the U.S. Patent and Trademark Office during prosecution of the '446 patent.
- (9) Attorneys at the law firm of Woodcock Washburn LLP are likely to have discoverable information relating to DePuy Mitek's alleged misuse of the '446 patent.
- (10) Individuals currently or formerly employed with Ethicon and/or DePuy Mitek are likely to have discoverable information relating to DePuy Mitek's alleged misuse of the '446 patent.
- (11) Individuals associated with United States Surgical Corporation are likely to have discoverable information relating to the alleged invalidity of the '446 patent.

Arthrex will identify and provide information about expert witnesses in accordance with Rule 26(a)(2) of the Federal Rules of Civil Procedure and the Joint Case Management Statement.

The above-listed witnesses who are or were employed by Arthrex can be contacted through Arthrex's counsel.

B. Documents, Data Compilations, and Tangible Things That Are in the Possession, Custody, or Control of Arthrex

Pursuant to Rule 26(a)(1)(B), Arthrex provides the following categorical description of the documents, data compilations, and tangible things that are in its possession, custody, or control and that may be used to support Arthrex's claims or

defenses. These categories include:

- (1)The '446 patent and its prosecution history;
- (2) Prior art and prosecution histories of the prior art;
- Documents relating to Arthrex's FiberWire™ suture products; (3)
- (4)Samples of Arthrex's FiberWire™ suture products;
- Documents relating to Arthrex's sales of its FiberWire<sup>TM</sup> suture (5) products; and
- (6) Correspondence between counsel for Arthrex and counsel for DePuy Mitek.

The parties have agreed to exchange initial disclosure documents on February 25, 2005.

Computation of Categories of Damages

Arthrex cannot provide a computation of its attorney fees and costs incurred in connection with this litigation until the litigation is concluded.

Insurance Agreements Under Which an Insurance Business May Be Liable to Satisfy a Judgment Against Arthrex or Indemnify or Reimburse Arthrex D.

Arthrex is not aware of any relevant insurance agreements.

Dated: February 8, 2005

By: \_

Charles W. Saber Stephen A. Soffen Salvatore P. Tamburo

DICKSTEIN SHAPIRO MORIN

& OSHINSKY LLP 2101 L Street NW

Washington, D.C. 20037-1526 Telephone: (202) 861-9116

Facsimile: (202) 887-0689

Christopher Weld, Jr. (BBO # 522230) Raymond P. Ausrotas (BBO # 640315) TODD & WELD LLP

28 State Street, 31st Floor Boston, MA 02109

Telephone: (617) 720-2626 Facsimile: (617) 227-5777

Counsel for Defendant Arthrex, Inc.

### CERTIFICATE OF SERVICE

It is hereby certified that a true and correct copy of the foregoing Defendant Arthrex, Inc.'s Initial Disclosures has been served by facsimile and first class mail on the following counsel for Depuy Mitek, Inc. on this 8th day of February 2005:

Jonatha Rochste

Lynn A. Malinoski Woodcock Washburn, LLP One Liberty Place, 46th Floor Philadelphia, PA. 19103 215-568-3439 (fax)

Daniel J. Gleason Nutter McClennan & Fish LLP World Trade Center West 155 Seaport Boulevard Boston, MA 02210-2604 617-310-9000 (fax)

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## IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc.	
Plaintiff,	) ) )
vs.	) Case No. 04-12457 PBS
Arthrex, Inc.,	) )
Defendant.	) ) )

#### **DEFENDANT PEARSALLS, LIMITED'S INITIAL DISCLOSURES**

Pursuant to Rule 26(a)(1) of the Federal Rules of Civil Procedure, Defendant Pearsalls, Limited ("Pearsalls"), by and through its counsel, makes the following disclosures. Pearsalls reserves the right to supplement, amend or otherwise revise the information contained herein upon further investigation, the receipt of additional information during discovery and the course of these proceedings.

A. Individuals Likely to Have Discoverable Information That Pearsalls May
<u>Use to Support Its Claims or Defenses</u>

Pursuant to Rule 26(a)(1)(A), Pearsalls notifies DePuy Mitek, Inc. ("DePuy Mitek") that the following individuals at this time are likely to have discoverable information that Pearsalls may use to support its claims or defenses:

(1) Reinhold Schmieding, President and Founder, Arthrex, Inc., 1370 Creekside Boulevard, Naples, Florida 34108, (800) 933-7001. Mr. Schmieding is familiar with the development, marketing and sales of Arthrex's FiberWire<sup>TM</sup> surgical suture products and decisions about offering those products into the market. Further, Mr. Schmieding is familiar with the state of the art for surgical suture products.

- (2) R. Donald Grafton, 4218 Skyway Drive, Naples, Florida 34112-1902. Mr. Grafton, a former employee of Arthrex, is familiar with the development, marketing and sales of Arthrex's FiberWire<sup>TM</sup> surgical suture products and decisions about offering those products into the market. Further, Mr. Grafton is familiar with the state of the art for surgical suture products.
- (3) D. Lawson Lyon, Managing Director, Pearsalls, Limited, Little
  Burrow Farm, Broadclyst, Exeter, Devon, EXS 3JA, United Kingdom, is familiar with the
  development, characteristics, marketing and manufacturing of heterogeneous braids
  used in Arthrex's FiberWire<sup>TM</sup> surgical suture products. Mr. Lyon is also familiar with
  Arthrex's FiberWire<sup>TM</sup> surgical suture and the corporate structure and history of
  Pearsalls.
- (4) Brian Hallet, Research and Development Manager, Pearsalls, Limited, 64, Priorswood Road, Taunton, Somerset, TA2 7PT, United Kingdom, is familiar with the development, characteristics and manufacturing of heterogeneous braids used in Arthrex's FiberWire™ surgical suture products. Mr. Hallet is also familiar with Arthrex's FiberWire™ surgical suture.
- (5) James Banks, Comptroller and General Manager, Pearsalls, Limited, is familiar with the sales of heterogeneous braids used in Arthrex's FiberWire™ surgical suture products.
- (6) Arthur Taylor, Jr., Plainfield, New Jersey, is likely to have discoverable information relating to the '446 patent and to inequitable conduct alleged to have been committed before the U.S. Patent and Trademark Office during prosecution of the '446 patent.

- (7) Mark Steckel, Maineville, Ohio, is likely to have discoverable information relating to the '446 patent and to inequitable conduct alleged to have been committed before the U.S. Patent and Trademark Office during prosecution of the '446 patent.
- (8) Attorneys for Ethicon, Inc. ("Ethicon") and others on behalf of Ethicon who were involved in the prosecution of the '446 patent are likely to have discoverable information relating to the prosecution of the '446 patent and to inequitable conduct alleged to have been committed before the U.S. Patent and Trademark Office during prosecution of the '446 patent.
- (9) Attorneys at the law firm of Woodcock Washburn LLP are likely to have discoverable information relating to DePuy Mitek's alleged misuse of the '446 patent.
- (10) Individuals currently or formerly employed with Ethicon and/or DePuy Mitek are likely to have discoverable information relating to DePuy Mitek's alleged misuse of the '446 patent.
- (11) Individuals associated with United States Surgical Corporation are likely to have discoverable information relating to the alleged invalidity of the '446 patent.

Pearsalls will identify and provide information about expert witnesses in accordance with Rule 26(a)(2) of the Federal Rules of Civil Procedure and the Joint Case Management Statement.

The above-listed witnesses who are or were employed by either Arthrex or Pearsalls can be contacted through Arthrex's and Pearsalls' counsel.

B. Documents, Data Compilations, and Tangible Things That Are in the Possession, Custody, or Control of Pearsalls

Pursuant to Rule 26(a)(1)(B), Pearsalls provides the following categorical description of the documents, data compilations, and tangible things that are in its possession, custody, or control and that may be used to support its claims or defenses. These categories include:

- (1)Documents relating to the heterogeneous braids used in Arthrex's FiberWire™ suture products;
- (2)Samples of the heterogeneous braids used in Arthrex's FiberWire<sup>TM</sup> suture products; and
- (3)Documents relating to Pearsalls' sales of its heterogeneous braids used in Arthrex's FiberWire $^{TM}$  suture products.

Pearsalls will produce initial disclosure documents and documents responsive to DePuy Mitek's requests for documents on or about the week of November 28, 2005.

#### C. Computation of Categories of Damages

Pearsalls cannot provide a computation of its attorney fees and costs incurred in connection with this litigation until the litigation is concluded.

D. Insurance Agreements Under Which an Insurance Business May Be Liable to Satisfy a Judgment Against Pearsalls or Indemnify or Reimburse Pearsalls Pearsalls is not aware of any relevant insurance agreements.

Dated: November 4, 2005

Christopher Weld, Jr. (BBO # 522230)
Raymond P. Ausrotas (BBO # 640315)
TODD & WELD LLP
28 State Street, 31st Floor
Boston, MA 02109
Telephone: (617) 720-2626
Facsimile: (617) 227-5777

Counsel for Defendants Arthrex, Inc. and Pearsalls, Limited

# **CERTIFICATE OF SERVICE**

It is hereby certified that a true and correct copy of the foregoing Defendant Pearsalls, Limited's Initial Disclosures has been served by facsimile and first class mail on the following counsel for Depuy Mitek, Inc. on this 4th day of November 2005:

Lynn A. Malinoski Woodcock Washburn, LLP One Liberty Place, 46th Floor Philadelphia, PA. 19103 Telephone: (215) 568-3100 Facsimile: (215) 568-3439

Daniel J. Gleason Nutter McClennan & Fish LLP World Trade Center West 155 Seaport Boulevard Boston, MA 02210-2604 Telephone: (617) 439-2000

Facsimile: (617) 310-9000

# IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc.	)
a Massachusetts Corporation	)
Plaintiff,	)
v.	) Civil No. 04-12457 PBS
Arthrex, Inc. a Delaware Corporation and	) ) )
Pearsalls Ltd. a Private Limited Company of the United Kingdom	) ) )
Defendants.	) )

### **DePuy Mitek's Supplemental Initial Disclosure**

Pursuant to FED. R. CIV. P. 26(a)(1), DePuy Mitek, Inc. ("DePuy Mitek") makes the following Initial Disclosure to Pearsalls Ltd. ("Pearsalls"). This Initial Disclosure is based upon information reasonably available to DePuy Mitek at the present stage of this litigation and the issues as presently defined by the pleadings. DePuy Mitek reserves the right to supplement, revise, or otherwise amend the information contained herein.

#### I. PERSONS LIKELY TO HAVE DISCOVERABLE INFORMATION

The following list identifies those individuals presently known to DePuy Mitek who are likely to have discoverable information that DePuy Mitek may use to support its anticipated claims and defenses, unless solely for impeachment. Each of the individuals listed in the chart below is represented by Woodcock Washburn. DePuy Mitek reserves the right to supplement this list as a result of further investigation, discovery, or otherwise.

Individual	Address and Telephone,	Information That the
	If Known	Person May Have
Arthur Taylor, Jr.	209 Loft Lane, Apt. 71, Raleigh, NC 27609	Inventor
Mark Steckel	Boston Scientific 24 Prime Park Way Natick, MA 01760	Inventor
	(508) 647-5300	
Gary B. McAlister Director of Research & Development Processes	DePuy Mitek 249 Vanderbilt Avenue Norwood, MA. 02062 (781) 251-2700	Technical information relating to suture products sold by DePuy Mitek.
Shelby Cook Engineer	DePuy Mitek 249 Vanderbilt Avenue Norwood, MA. 02062 (781) 251-2700	Technical information relating to suture products sold by DePuy Mitek.
Mike McBreen VP Sales & Marketing, DePuy Mitek.	DePuy Mitek 249 Vanderbilt Avenue Norwood, MA. 02062 (781) 251-2700	Sales of suture products; damages related financial information.
Rick Gilson Director of Marketing for the Shoulder	DePuy Mitek 249 Vanderbilt Avenue Norwood, MA. 02062 (781) 251-2700	Market for suture products; marketing of suture products; and damages related issues.
Matthew Goodwin, Esq.	Johnson & Johnson Law Department One Johnson & Johnson Plaza New Brunswick, NJ 08933 732-524-0400	Prosecution of the Hunter Patent
Hal Woodrow, Esq.	Johnson & Johnson Law Department Ethicon, Inc.	Prosecution of the Hunter Patent.
Dennis Jamiolkowski	ETHICON Products Worldwide, a division of ETHICON, Inc. a Johnson & Johnson company Somerville, NJ 08876-0151	Design and development of invention
Neil Weber Vice President, US Marketing	DePuy Mitek 249 Vanderbilt Avenue Norwood, MA. 02062 (781) 251-2700	Market for suture products; marketing of suture products; and damages related issues.

#### II. A DESCRIPTION BY CATEGORY AND LOCATION OF ALL DOCUMENTS, DATA COMPILATIONS, AND TANGIBLE THINGS THAT ARE IN THE POSSESSION, CUSTODY, OR CONTROL OF DEPUY MITEK AND THAT DEPUY MITEK MAY USE TO SUPPORT ITS CLAIMS OR DEFENSES

DePuy Mitek identifies the following categories of documents in accordance with FED. R. CIV. P. 26(a)(1)(B).

DePuy Mitek has within its possession, custody, and control documents, data compilations, and/or other tangible things falling under the general categories listed below. These may include documents subject to the attorney-client and/or work product privilege. The disclosure herein is made without a waiver of these privileges.

- Documents relating to U.S. Patent No. 5,314,446 and its prosecution history.
- Documents relating to the development of the claimed subject matter.
- Documents relating to DePuy Mitek's suture products that compete with the FiberWire<sup>TM</sup> products.
- Documents relating to Arthrex's suture products, including those incorporating FiberWire<sup>TM</sup>.
- Documents relating to the damages suffered by DePuy Mitek as a result of Arthrex's infringement.

DePuy Mitek reserves the right to supplement its initial disclosure and any production at such time as additional information comes to its attention as a result of further investigation, discovery, or otherwise. DePuy Mitek proposes that the parties agree to a mutually convenient date for exchanging initial disclosure documents.

Despite Ethicon not being a party to this action, and despite Arthrex not serving proper discovery on Ethicon, Ethicon, without waiving objections, agreed to produce documents within its possession, custody, and control, data compilations, and/or other tangible things falling under the general categories listed below. These may include documents subject to the attorney-client and/or work product privilege. The disclosure herein is made without a waiver of these privileges.

- Documents relating to U.S. Patent No. 5,314,446 and its prosecution history.
- Documents relating to the claimed subject matter.
- Documents relating to sutures that compete with the FiberWire<sup>TM</sup> products.
- Documents relating to Arthrex's suture products, including those incorporating FiberWire<sup>TM</sup>.
- Documents relating to damages.

#### III. COMPUTATION OF DAMAGES

DePuy Mitek will seek damages as permitted by 35 U.S.C. §284 resulting from Arthrex's and Pearsalls' infringement of the 446 Patent, including lost profits and/or a reasonable royalty. DePuy Mitek also will seek increased damages and attorneys' fees as a result of Arthrex's willful infringement. DePuy Mitek is not able to provide any calculation of such damages at this time because necessary facts are within Pearsalls' control. As set forth in the Advisory Committee notes to Rule 26(a)(1): "a party would not be expected to provide a calculation of damages which, as in many patent infringement actions, depends on information in the possession of another party or person."

#### IV. INSURANCE OR INDEMNITY AGREEMENTS

DePuy Mitek is not presently aware of any insurance agreement under which any person carrying on an insurance business may be liable to satisfy part or all of a judgment that may be entered in this action or to indemnify or reimburse for payments made to satisfy the judgment.

DEPUY MITEK, INC.,

By its attorneys,

Daniel J. Gleason (BBO #194900)

Michelle Chassereau Jackson (BBO 654825)

NUTTER MCCLENNEN & FISH LLP

World Trade Center West 155 Seaport Boulevard Boston, MA. 02210-2604 617-439-2000

Dianne B. Elderkin Lynn A. Malinoski Michael J. Bonella Erich M. Falke WOODCOCK WASHBURN LLP One Liberty Place - 46th Floor 17th and Market Streets Philadelphia, PA 19103 (215) 568-3100

Dated: October 19, 2005

#### **CERTIFICATE OF SERVICE**

I certify that the foregoing DePuy Mitek Inc.'s Initial Disclosures were served by facsimile on counsel for Arthrex and Pearsalls on October 19, 2005 as identified below:

> Charles W. Saber Dickstein, Shapiro, Morin & Ochinsky, LLP 2101 L. Street, NW Washington, DC 20037-1526. Fax: (202) 887-0689

Christopher Weld, Jr. Todd & Weld LLP 28 State Street, 31st Floor Boston, MA 02109 Fax: (617) 227-5777

Dated: October 19, 2005

Jupan a. Melinski

# THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

DEPUY MITEK, INC., a Massachusetts Corporation,

Plaintiff,

Civil No. 04-12457 PBS

٧.

ARTHREX, INC.,
a Delaware Corporation and

PEARSALLS LTD.
a Private Limited Company of
the United Kingdom

Defendants.

#### DePuy Mitek's Second Supplemental Initial Disclosure

Pursuant to FED. R. CIV. P. 26(a)(1), DePuy Mitek, Inc. ("DePuy Mitek") makes the following supplemental Initial Disclosure to Arthrex, Inc. ("Arthrex") and Pearsalls Ltd. ("Pearsalls"). This Initial Disclosure is based upon information reasonably available to DePuy Mitek at the present stage of this litigation and the issues as presently defined by the pleadings. DePuy Mitek reserves the right to supplement, revise, or otherwise amend the information contained herein.

#### I. PERSONS LIKELY TO HAVE DISCOVERABLE INFORMATION

The following list identifies those individuals presently known to DePuy Mitek who are likely to have discoverable information that DePuy Mitek may use to support its anticipated claims and defenses, unless solely for impeachment. DePuy Mitek reserves the right to supplement this list as a result of further investigation, discovery, or otherwise.

Individual	Address and Telephone,	Information That the
	If Known	Person May Have
Arthur Taylor, Jr.	209 Loft Lane, Apt. 71,	Inventor
	Raleigh, NC 27609	
	(retired and represented by	
	Woodcock Washburn)	
Mark Steckel	Boston Scientific	Inventor
	24 Prime Park Way	
	Natick, MA 01760	
	(508) 647-5300	
Gary B. McAlister	DePuy Mitek	Technical information
Director of Research &	249 Vanderbilt Avenue	relating to suture products
Development Processes	Norwood, MA. 02062	sold by DePuy Mitek.
- Theorem	(781) 251-2700	
Shelby Cook	DePuy Mitek	Technical information
Engineer	249 Vanderbilt Avenue	relating to suture products
	Norwood, MA. 02062	sold by DePuy Mitek.
	(781) 251-2700	
Mike McBreen	DePuy Mitek	Sales of suture products;
VP Sales & Marketing,	249 Vanderbilt Avenue	damages related financial
DePuy Mitek.	Norwood, MA. 02062	information.
	(781) 251-2700	
Rick Gilson	DePuy Mitek	Market for suture products;
Director of Marketing for	249 Vanderbilt Avenue	marketing of suture
the Shoulder	Norwood, MA. 02062	products; and damages
-181	(781) 251-2700	related issues.
Matthew Goodwin, Esq.	Johnson & Johnson Law	Prosecution of the Hunter
	Department	Patent
	One Johnson & Johnson	
	Plaza	
	New Brunswick, NJ 08933	
	732-524-0400	
Hal Woodrow, Esq.	Johnson & Johnson Law	Prosecution of the Hunter
	Department	Patent.
	Ethicon, Inc.	
Dennis Jamiolkowski	ETHICON Products	Design and development of
	Worldwide, a division of	invention
	EHTICON, Inc. a Johnson	
	& Johnson company	
	Somerville, NJ 08876-0151	
Neil Weber	DePuy Mitek	Market for suture products;
Vice President, US	249 Vanderbilt Avenue	marketing of suture
Marketing	Norwood, MA. 02062	products; and damages
	(781) 251-2700	related issues.
Michel Paul	DePuy Mitek	Information relating to
CEO	249 Vanderbilt Avenue	DePuy Mitek's business, its

Norwood, MA. 02062 (781) 251-2700	corporate structure, corporate history, products, and how Arthrex's FiberWire products have
	affected Mitek's business.

# II. A DESCRIPTION BY CATEGORY AND LOCATION OF ALL DOCUMENTS, DATA COMPILATIONS, AND TANGIBLE THINGS THAT ARE IN THE POSSESSION, CUSTODY, OR CONTROL OF DEPUY MITEK AND THAT DEPUY MITEK MAY USE TO SUPPORT ITS CLAIMS OR DEFENSES

DePuy Mitek identifies the following categories of documents in accordance with FED. R. CIV. P. 26(a)(1)(B).

DePuy Mitek has within its possession, custody, and control documents, data compilations, and/or other tangible things falling under the general categories listed below. These may include documents subject to the attorney-client and/or work product privilege. The disclosure herein is made without a waiver of these privileges.

- Documents relating to U.S. Patent No. 5,314,446 and its prosecution history.
- Documents relating to the development of the claimed subject matter.
- Documents relating to DePuy Mitek's suture products that compete with the FiberWire™ products.
- Documents relating to Arthrex's suture products, including those incorporating FiberWire™.
- Documents relating to the damages suffered by DePuy Mitek as a result of Arthrex's infringement.

DePuy Mitek reserves the right to supplement its initial disclosure and any production at such time as additional information comes to its attention as a result of further investigation, discovery, or otherwise. DePuy Mitek proposes that the parties agree to a mutually convenient date for exchanging initial disclosure documents.

Despite Ethicon not being a party to this action, and despite Arthrex not serving proper discovery on Ethicon, Ethicon, without waiving objections, agreed to produce documents within its possession, custody, and control, data compilations, and/or other tangible things falling under the general categories listed below. These may include documents subject to the attorney-client and/or work product privilege. The disclosure herein is made without a waiver of these privileges.

- Documents relating to U.S. Patent No. 5,314,446 and its prosecution history.
- Documents relating to the claimed subject matter.
- Documents relating to sutures that compete with the FiberWire<sup>TM</sup> products.
- Documents relating to Arthrex's suture products, including those incorporating FiberWire<sup>TM</sup>.
- Documents relating to damages.

#### III. COMPUTATION OF DAMAGES

DePuy Mitek will seek damages as permitted by 35 U.S.C. §284 resulting from Arthrex's and Pearsalls' infringement of the 446 Patent, including lost profits and/or a reasonable royalty. DePuy Mitek also will seek increased damages and attorneys' fees as a result of Arthrex's willful infringement. DePuy Mitek is not able to provide any calculation of such damages at this time because necessary facts are within Arthrex's and Pearsalls' control. As set forth in the Advisory Committee notes to Rule 26(a)(1): "a party would not be expected to provide a calculation of damages which, as in many patent infringement actions, depends on information in the possession of another party or person."

#### IV. INSURANCE OR INDEMNITY AGREEMENTS

DePuy Mitek is not presently aware of any insurance agreement under which any person carrying on an insurance business may be liable to satisfy part or all of a judgment that may be entered in this action or to indemnify or reimburse for payments made to satisfy the judgment.

DEPUY MITEK, INC.,

By its attorneys,

Daniel J. Gleason (BBO #194900)

Michelle Chassereau Jackson (BBO #654825)

NUTTER MCCLENNEN & FISH LLP

World Trade Center West 155 Seaport Boulevard

Boston, MA. 02210-2604

(617) 439-2000

Dianne B. Elderkin

Lynn A. Malinoski

Michael J. Bonella

Erich M. Falke

WOODCOCK WASHBURN LLP

One Liberty Place - 46th Floor

17th and Market Streets

Philadelphia, PA 19103

(215) 568-3100

Dated: January 18, 2006

#### CERTIFICATE OF SERVICE

I certify that the foregoing **DePuy Mitek Inc.'s Second Supplemental Initial Disclosure** was served by facsimile on counsel for Arthrex and Pearsalls on January 18, 2006 as identified below:

Charles W. Saber, Esq. Dickstein Shapiro Morin & Oshinsky LLP 2101 L Street, N.W. Washington, D.C. 20037 Fax: (202) 887-0689

Christopher Weld, Jr. Todd & Weld LLP 28 State Street, 31<sup>st</sup> Floor Boston, MA 02109 Fax: (617) 227-5777

Dated: January 18, 2006

## THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

DEPUY MITEK, INC., a Massachusetts Corporation,

Plaintiff,

Civil No. 04-12457 PBS

v.

ARTHREX, INC., a Delaware Corporation and

PEARSALLS LTD. a Private Limited Company of the United Kingdom

Defendants.

#### DePuy Mitek's Third Supplemental Initial Disclosure

Pursuant to FED. R. CIV. P. 26(a)(1), DePuy Mitek, Inc. ("DePuy Mitek") makes the following supplemental Initial Disclosure to Arthrex, Inc. ("Arthrex") and Pearsalls Ltd. ("Pearsalls"). This Initial Disclosure is based upon information reasonably available to DePuy Mitek at the present stage of this litigation and the issues as presently defined by the pleadings. DePuy Mitek reserves the right to supplement, revise, or otherwise amend the information contained herein.

#### T. PERSONS LIKELY TO HAVE DISCOVERABLE INFORMATION

The following list identifies those individuals presently known to DePuy Mitek who are likely to have discoverable information that DePuy Mitek may use to support its anticipated claims and defenses, unless solely for impeachment. DePuy Mitek reserves the right to supplement this list as a result of further investigation, discovery, or otherwise.

Norwood, MA. 02062 (781) 251-2700	corporate structure, corporate history, products, and how Arthrex's FiberWire products have affected Mitek's business.
--------------------------------------	--

# DePuy Mitek's Supplemental Disclosure of Persons Likely To Have **Discoverable Information:**

The following supplemental list identifies those additional individuals presently known to DePuy Mitek who are likely to have discoverable information that DePuy Mitek may use to support its anticipated claims and defenses, unless solely for impeachment. DePuy Mitek reserves the right to supplement this list as a result of further investigation, discovery or otherwise.

Todd Tetrault	DePuy Mitek	Sales of suture products;
	249 Vanderbilt Avenue	financial information.
	Norwood, MA. 02062	
	(781) 251-2700	
Steve Muller	DePuy Mitek	Market for suture products
	249 Vanderbilt Avenue	and marketing of suture
	Norwood, MA. 02062	products.
	(781) 251-2700	
E. Richard Skula	Johnson and Johnson Law	Communications with
	Department	Arthrex regarding the 446
	One Johnson and Johnson	patent and Arthrex's notice
	Plaza	of the 446 patent.
	New Brunswick, NJ 08903	
Katie Seppa	Ethicon, Inc.	Technical information
	Rte 22 West	relating to Ethicon suture
	Somerville, N.J., 08876	products.
Kyle Kichline	Ethicon, Inc.	Financial information
	Rte 22 West	related to Ethicon's suture
	Somerville, N.J., 08876	products.
Alistair Simpson	Ethicon, Inc.	Marketing information
	Rte 22 West	related to Ethicon's suture
	Somerville, N.J., 08876	products.

II. A DESCRIPTION BY CATEGORY AND LOCATION OF ALL DOCUMENTS, DATA COMPILATIONS, AND TANGIBLE THINGS THAT ARE IN THE POSSESSION, CUSTODY, OR CONTROL OF DEPUY MITEK AND THAT DEPUY MITEK MAY USE TO SUPPORT ITS CLAIMS OR DEFENSES

DePuy Mitek identifies the following categories of documents in accordance with FED. R. CIV. P. 26(a)(1)(B).

DePuy Mitek has within its possession, custody, and control documents, data compilations, and/or other tangible things falling under the general categories listed below. These may include documents subject to the attorney-client and/or work product privilege. The disclosure herein is made without a waiver of these privileges.

- Documents relating to U.S. Patent No. 5,314,446 and its prosecution history.
- Documents relating to the development of the claimed subject matter.
- Documents relating to DePuy Mitek's suture products that compete with the FiberWire™ products.
- Documents relating to Arthrex's suture products, including those incorporating FiberWire<sup>TM</sup>.
- Documents relating to the damages suffered by DePuy Mitek as a result of Arthrex's infringement.

DePuy Mitek reserves the right to supplement its initial disclosure and any production at such time as additional information comes to its attention as a result of further investigation, discovery, or otherwise. DePuy Mitek proposes that the parties agree to a mutually convenient date for exchanging initial disclosure documents.

Despite Ethicon not being a party to this action, and despite Arthrex not serving proper discovery on Ethicon, Ethicon, without waiving objections, agreed to produce documents within its possession, custody, and control, data compilations, and/or other tangible things falling under the general categories listed below. These may include documents subject to the attorney-client and/or work product privilege. The disclosure herein is made without a waiver of these privileges.

- Documents relating to U.S. Patent No. 5,314,446 and its prosecution history.
- Documents relating to the claimed subject matter.
- Documents relating to sutures that compete with the FiberWire<sup>TM</sup> products.
- Documents relating to Arthrex's suture products, including those incorporating FiberWire<sup>TM</sup>.
- Documents relating to damages.

#### Ш. COMPUTATION OF DAMAGES

DePuy Mitek will seek damages as permitted by 35 U.S.C. §284 resulting from Arthrex's and Pearsalls' infringement of the 446 Patent, including lost profits and/or a reasonable royalty. DePuy Mitek also will seek increased damages and attorneys' fees as a result of Arthrex's willful infringement. DePuy Mitek is not able to provide any calculation of such damages at this time because necessary facts are within Arthrex's and Pearsalls' control. As set forth in the Advisory Committee notes to Rule 26(a)(1): "a party would not be expected to provide a calculation of damages which, as in many patent infringement actions, depends on information in the possession of another party or person."

#### IV. INSURANCE OR INDEMNITY AGREEMENTS

DePuy Mitek is not presently aware of any insurance agreement under which any person carrying on an insurance business may be liable to satisfy part or all of a judgment that may be entered in this action or to indemnify or reimburse for payments made to satisfy the judgment.

DEPUY MITEK, INC.,

By its attorneys,

Dani J. Gleason (BBO#194900)

Michelle Chassereau Jackson (BBO #654825)

NUTTER MCCLENNEN & FISH LLP

World Trade Center West 155 Seaport Boulevard

Boston, MA. 02210-2604

(617) 439-2000

Dianne B. Elderkin

Lynn A. Malinoski

Michael J. Bonella

Erich M. Falke

WOODCOCK WASHBURN LLP

One Liberty Place - 46th Floor

17th and Market Streets

Philadelphia, PA 19103

(215) 568-3100

Dated: February 2, 2006

#### CERTIFICATE OF SERVICE

I certify that the foregoing DePuy Mitek Inc.'s Third Supplemental Initial Disclosure was served by facsimile on counsel for Arthrex and Pearsalls on February 2, 2006 as identified below:

> Charles W. Saber, Esq. Dickstein Shapiro Morin & Oshinsky LLP 2101 L Street, N.W. Washington, D.C. 20037 Fax: (202) 887-0689

Christopher Weld, Jr. Todd & Weld LLP 28 State Street, 31st Floor Boston, MA 02109 Fax: (617) 227-5777

Dated: February 2, 2006

# IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc. a Massachusetts Corporation	)
Plaintiff.	)
<b>v.</b>	) Civil No. 04-12457 PBS
Arthrex, Inc. a Delaware Corporation	) ) )
Defendant.	)

# DePuy Mitek's First Set of Interrogatories to Arthrex, Inc.

# **Definitions**

1. DePuy Mitek incorporates by reference the definitions set forth in its First Set of Requests for Documents and Things to Arthrex, Inc.

Identify by trade name and Arthrex catalog number (i.e., the numbers Arthrex has assigned to products in its product catalogs) each Braided Suture Product and Convoyed Braided Suture Product that Arthrex has sold, offered for sale, made, or used anywhere in the world or imported into the United States and the first date when each such product was sold or offered for sale.

For each sale of each Braided Suture Product and Convoyed Braided Suture Product worldwide identify where and by whom (*e.g.*, by name, address, and telephone number) each Braided Suture Product and Convoyed Braided Suture Product was manufactured.

Describe all facts that support Arthrex's contentions that it has not infringed any claim of the Patent-in-Suit as set forth in ¶¶12-13 of Arthrex's Answer including, but not limited to,

- (a) identifying each element of each claim of the Patent-in-Suit that Arthrex contends is literally absent from each Arthrex Braided Suture Product;
- (b) explain (i) what Arthrex contends the basic and novel characteristics of the invention claimed in the Patent-in-Suit are; (ii) each contention that Arthrex does not infringe the Patent-in-Suit because its Braided Suture Products have a material that materially affects the claims' basic and novel characteristics; and (iii) what the material effect on the claims' basic and novel characteristics are by an alleged material in Arthrex's Braided Suture Products.
- (c) explain any Arthrex contention that any alleged absent claim element is not satisfied under the doctrine of equivalents by describing all alleged substantial differences between the claim and Arthrex's Braided Suture Products and any reason why the function/way/result test is not satisfied for each Arthrex Braided Suture Product; and
- (d) explain all facts that support any prosecution history estoppel contention with respect to the Patent-in-Suit including but not limited to the specific pages and lines of the prosecution history that Arthrex contends evidence prosecution history estoppel; and
- (e) identify the tensile strength and bending strength and rigidity of each Arthrex Braided Suture Product with and without a coating and how those properties were determined and what samples were used in any such determination.

Identify (i) when Arthrex first became aware of the Patent-in-Suit, (ii) who, if anyone, at Arthrex decided to market and continue to market the Arthrex's Braided Suture Products in light of Arthrex's knowledge of the Patent-in-Suit; (iii) what opinions (identified by date and author), if any, that person relied on; and (iv) and all other facts that support Arthrex's contention that it has not willfully infringed the Patent-in-Suit.

To the extent that Arthrex contends that any claim of the Hunter patent is invalid under 35 U.S.C. § 102 or 103 (Answer at ¶¶9, 10):

- (a) identify each item of prior art upon which Arthrex relies, and make an element-by-element application (providing specific citation to the relevant portions of the prior art) of each allegedly invalid claim to each item of prior art, explaining in detail the grounds for any allegation of invalidity under 35 U.S.C. §102; and
- (b) state the factual basis for any contention that any claim of the Patent-in-Suit is invalid under 35 U.S.C. §103, including specifically, Arthrex's contentions of the level of ordinary skill in the art, the similarities and differences between each item of prior art and each claim, the scope and content of the prior art, and any secondary considerations.

With respect to Arthrex's inequitable conduct defense and counterclaim:

- (a) identify all persons who allegedly committed inequitable conduct;
- (b) state all facts supporting Arthrex's contention that the such persons committed inequitable conduct; and
- (c) identify each piece of information that was allegedly withheld and each alleged misrepresentation and why the alleged withheld information or misrepresentation is material.

With respect to Arthrex's contentions that the asserted claims are invalid under 35 U.S.C. § 112 (Answer at Affirmative Defenses ¶11):

- (a) identify each claim of the Patent-in-Suit that is allegedly invalid under 35 U.S.C. §112; and
- (b) explain the factual basis for each such contention, and identify the specific section and statutory requirement of 35 U.S.C. §112 that allegedly has not been met.

State all facts that support Arthrex's laches defense (Answer at ¶14) including, but not limited to, what time period constitutes the "delay" alleged in ¶14 of Arthrex's Answer; what makes the delay "unreasonable and unjustified" as alleged in ¶14 of Arthrex's Answer; and Arthrex's alleged prejudice from the alleged "delay;" and why any such alleged prejudice is material.

Identify each person currently and previously employed by or associated with Arthrex who had or has responsibility for the following:

- (a) the design and development of each Arthrex Braided Suture Product;
- (b) the selection of materials and testing of the suture part of each Arthrex Braided Suture Product;
- (c) the manufacturing of each Arthrex Braided Suture Product; and
- (d) the marketing and sales of each Arthrex Braided Suture Product.

With respect to Arthrex's patent misuse defense alleged in ¶18 of its Answer explain what Arthrex contends the relevant product and geographic markets are, explain all facts that support any Arthrex contention that DePuy Mitek has or is likely to have market power in the relevant product and geographic markets; and explain all facts that support Arthrex's contention that DePuy Mitek "by virtue of its efforts to obtain, enforce, and use the '446 patent, knowing said patent to be invalid, uninfringed, and unenforceable, have misused said patent" (Arthrex's Answer at ¶18).

State whether Arthrex's Braided Suture Products and Convoyed Braided Suture Product have been commercially successful and if so the reasons for their success.

Identify each product (by trade name, manufacturer or seller, and other identifying information) that competes with Arthrex's Braided Suture Products and Convoyed Braided Suture Products and in what product and geographic markets each product competes with Arthrex's Braided Suture Products and Convoyed Braided Suture Products.

Identify any product that Arthrex contends is a non-infringing substitute and explain when any alleged non-infringing substitute was readily available to Arthrex, and explain all efforts required to switch from each Arthrex Braided Suture Product to any alleged readily available non-infringing substitute.

Identify each person whom Arthrex expects to call at trial or at the Markman hearing, including but not limited to expert witnesses, and state the qualifications of all persons listed, the subject matter, and the substance of the facts and opinions to which each person is expected to testify.

Case 1:04-cv-12457-PBS

DEPUY MITEK, INC.,

By its attorneys,

Dianne B. Elderkin Lynn A. Malinoski Michael J. Bonella Erich M. Falke

WOODCOCK WASHBURN LLP One Liberty Place - 46th Floor 17th and Market Streets Philadelphia, PA 19103 (215) 568-3100

Daniel J. Gleason (BBO #194900) Michelle Chassereau Jackson (BBO #654825) Nutter McClennen & Fish LLP World Trade Center West 155 Seaport Boulevard Boston, MA. 02210-2604 617-439-2000

# **CERTIFICATE OF SERVICE**

I certify that the foregoing **DePuy Mitek's First Set of Interrogatories to Arthrex, Inc.** was served by facsimile on the following:

Charles W. Saber Dickstein, Shapiro, Morin & Ochinsky, LLP 2101 L. Street, NW Washington, DC 20037-1526. Fax: (202) 887-0689

Christopher Weld, Jr. Todd & Weld LLP 28 State Street, 31<sup>st</sup> Floor Boston, MA 02109 Fax: (617) 227-5777

Dated: January 14, 2005

# IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

	)	
DePuy Mitek, Inc.	)	
a Massachusetts Corporation	)	
-	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No. 04-12457 PBS
	)	
Arthrex, Inc.	)	
a Delaware Corporation	)	
-	)	
Defendant.	)	
	)	

# ARTHREX, INC.'S OBJECTIONS AND ANSWERS TO DEPUY MITEK, INC.'S FIRST SET OF INTERROGATORIES

Pursuant to Rule 33 of the Federal Rules of Civil Procedure and Rule 33.1 of the Local Rules of the United States District Court for the District of Massachusetts,

Defendant Arthrex, Inc., ("Arthrex") hereby responds to Defendant DePuy Mitek, Inc.'s

("DePuy Mitek") First Set of Interrogatories. These responses are based on information reasonably available to Arthrex at the present time. Arthrex reserves the right to supplement these responses when, and if, additional information becomes available.

Arthrex also reserves the right to object on any ground at any time to these

Interrogatories. Arthrex further reserves the right to object on any ground to such other or supplemental Interrogatories DePuy Mitek may propound involving or relating to the subject matter of these Interrogatories.

# **GENERAL OBJECTIONS**

- Arthrex objects to DePuy Mitek's Interrogatories to the extent that they 1. seek discovery of information or documents exceeding, or seek to impose definitions and instructions exceeding, the permissible scope of discovery under the Federal Rules of Civil Procedure, the Local Rules of the Court and applicable case law.
- 2. Arthrex objects to DePuy Mitek's Interrogatories to the extent that they purport to require Arthrex to seek information or documents beyond that in its possession, custody, or control as such production is beyond the permissible scope of the Federal Rules of Civil Procedure and applicable law, and would further pose an unreasonable and undue burden and expense on Arthrex.
- 3. Arthrex objects to DePuy Mitek's Interrogatories to the extent that they seek information that is not relevant to the issues in this litigation or that is not reasonably calculated to lead to the discovery of admissible evidence.
- 4. Arthrex objects to DePuy Mitek's Interrogatories to the extent that they seek information that is subject to any judicial order, protective order, privacy interest, contractual obligation, non-disclosure agreement, confidentiality agreement or other such confidentiality obligation vis-à-vis to any third party. Without third party permission, Arthrex will not provide such information unless ordered to do so by the Court.
- 5. Arthrex objects to DePuy Mitek's Interrogatories to the extent that they seek trade secrets and/or confidential documents or information. However, subject to the foregoing general objections, Arthrex will provide requested information to which DePuy Mitek is entitled in accordance with a Protective Order, when entered.
- 6. Arthrex objects to DePuy Mitek's Interrogatories to the extent that they seek information or documents protected by the attorney-client privilege, the work product doctrine, and/or any other privilege or immunity. Arthrex will not produce

such protected information. Moreover, any inadvertent disclosure of such information, or any inadvertent disclosure of documents underlying that information, shall not be deemed a waiver of any privilege or immunity. Privileged documents that are otherwise responsive to any interrogatory will be identified on a privilege log in accordance with Rule 26(b)(5) of the Federal Rules of Civil Procedure.

- 7. Arthrex objects to DePuy Mitek's Interrogatories to the extent that they seek to impose an obligation of a continuing nature beyond that required by Rule 26(e) of the Federal Rules of Civil Procedure.
- 8. Arthrex objects to DePuy Mitek's Interrogatories as being overly broad and unduly burdensome to the extent that they seek information beyond what is available from a reasonable search of Arthrex's files likely to contain relevant or responsive documents and a reasonable inquiry of Arthrex's current employees.
- 9. Arthrex objects to DePuy Mitek's Interrogatories as being unduly burdensome to the extent that such requests seek duplicative or cumulative information or documents.
- 10. Arthrex objects to DePuy Mitek's Interrogatories as unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence or to the extent that they seek information relating to its activities outside of the United States.
- 11. Arthrex objects to DePuy Mitek's Interrogatories to the extent they seek information from and about experts and any such information to which DePuy Mitek is entitled will be provided in accordance with the Federal Rules of Civil Procedure and the Joint Case Management Statement filed by the parties and Scheduling Order issued by the Court.
- 12. Arthrex objects to these Interrogatories to the extent they seek information within the possession or control of DePuy Mitek.
- 13. Statements made herein regarding Arthrex's intention to provide information or documents responsive to any given Interrogatory does not necessarily DSMDB.1884420.1 3

indicate or imply the existence of any information or documents responsive thereto. Furthermore, any information provided or referred to herein is not deemed to be a waiver of Arthrex's objections as to the competency, relevance, privilege or admissibility as evidence in this or any subsequent proceeding or trial in this or any other action for any purpose whatsoever. In addition, Arthrex reserves the right to supplement or amend its response to the Interrogatories based upon information, documents, and things it receives during discovery or obtains upon further investigation.

- 14. Discovery in this matter has only recently begun. Arthrex is continuing its investigation to obtain information responsive to the Interrogatories. Therefore, the responses provided herein do not prejudice Arthrex's right to introduce documents or information discovered or deemed responsive subsequent to the date of these responses.
- 15. In gathering relevant and responsive information, Arthrex has interpreted the Interrogatories utilizing ordinary meanings of words and has expended reasonable efforts to identify information that appears responsive. To the extent that the Interrogatories purport to seek information other than as so interpreted, Arthrex objects on the ground that the Interrogatories are vague, ambiguous and overbroad.
- 16. Arthrex objects to DePuy Mitek's definition of "Braided Suture Product(s)," "Arthrex Braided Suture Products," "Convoyed Braided Suture Product(s)" and "Arthrex Convoyed Braided Suture Product(s)" as being overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence. Accordingly, to the extent DePuy Mitek's Interrogatories contain these defined terms, Arthrex's answers to those interrogatories are limited to either Arthrex's FiberWire® suture products, Arthrex products that incorporate its FiberWire® suture products, or both.

# **DEFINITIONS**

1. As used herein, the term "DePuy Mitek" includes Plaintiff DePuy Mitek, Inc. and each of its predecessors, successors, subsidiaries, divisions, parent companies, departments and other related entities involved in prosecuting and/or enforcing the '446 patent.

# **ANSWERS AND SPECIFIC OBJECTIONS**

The following Answers to DePuy Mitek's Interrogatories are made subject to and without waiver of the foregoing General Objections, and such General Objections are incorporated into each Answer as though fully set forth therein. To the extent particular General Objections are restated in an Answer, they are provided because they are particularly applicable to the specific Interrogatory and such inclusion is not to be construed as a waiver of any other General Objections.

## **INTERROGATORY NO. 1.**

Identify by trade name and Arthrex catalog number (i.e., the numbers Arthrex has assigned to products in its product catalogs) each Braided Suture Product and Convoyed Braided Suture Product that Arthrex has sold, offered for sale, made, or used anywhere in the world or imported into the United States and the first date when each such product was sold or offered for sale.

#### **RESPONSE**

Arthrex objects to this Interrogatory as being overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence. The terms "Braided Suture Product" and "Convoyed Braided Suture Product," as defined by DePuy Mitek, are overly broad and include products not relevant to the present lawsuit. Arthrex further objects to this Interrogatory to the extent that it seeks information relating to its activities entirely outside of the United States. Subject to and without waiving its general and specific objections, Arthrex answers:

Non-privileged document(s) from which information responsive to this Interrogatory may be derived or ascertained will be produced pursuant to Rule 33(d) of

the Federal Rules of Civil Procedure and Rule 33.1 of the Court. Such document(s) will contain a heading "First Sale of Part #'s with FiberWire." Such document(s) will be a compilation of Arthrex catalog numbers and will include a date of first sale for each catalog number.

#### **INTERROGATORY NO. 2.**

For each sale of each Braided Suture Product and Convoyed Braided Suture Product worldwide identify where and by whom (e.g., by name, address, and telephone number) each Braided Suture Product and Convoyed Braided Suture Product was manufactured.

#### **RESPONSE**

Arthrex objects to this Interrogatory as being overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence. The terms "Braided Suture Product" and "Convoyed Braided Suture Product," as defined by DePuy Mitek, are overly broad and include products not relevant to the present action. Arthrex further objects to this Interrogatory to the extent it seeks information relating to its sales activities entirely outside of the United States. Subject to and without waiving its general and specific objections, Arthrex answers:

Arthrex's FiberWire® sutures are manufactured by Pearsalls Limited, Tankred Street, Taunton, Somerset, TA11RY, England, (01823) 253198.

### **INTERROGATORY NO. 3.**

Describe all facts that support Arthrex's contentions that it has not infringed any claim of the Patent-in-Suit as set forth in ¶¶ 12-13 of Arthrex's Answer including, but not limited to,

7

- (a) identifying each element of each claim of the Patent-in-Suit that Arthrex contends is literally absent from each Arthrex Braided Suture Product;
- (b) explain (i) what Arthrex contends the basic and novel characteristics of the invention claimed in the Patent-in-Suit are; (ii) each contention that Arthrex does not infringe the Patent-in-Suit because its Braided Suture Products have a material that materially affects the claims' basic and novel characteristics; and (iii) what the material effect on the claims' basic and novel characteristics are by an alleged material in Arthrex's Braided Suture Products.
- (c) explain any Arthrex contention that any alleged absent claim element is not satisfied under the doctrine of equivalents by describing all alleged substantial differences between the claim and Arthrex's Braided Suture Products and any reason why the function/way/result test is not satisfied for each Arthrex Braided Suture Product; and
- (d) explain all facts that support any prosecution history estoppel contention with respect to the Patent-in-Suit including but not limited to the specific pages and lines of the prosecution history that Arthrex contends evidence prosecution history estoppel; and
- (e) identify the tensile strength and bending strength and rigidity of each Arthrex Braided Suture Product with and without a coating and how those properties were determined and what samples were used in any such determination.

#### RESPONSE

Arthrex objects to this Interrogatory as being overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence. The terms "Braided Suture Product" and "Arthrex Braided Suture Product" as defined by DePuy Mitek, are overly broad and include products not relevant to the present lawsuit. Arthrex also objects to this Interrogatory as premature since DePuy Mitek has DSMDB.1884420.1

not yet identified which claim(s) of the '446 patent it is asserting, the basis for its infringement allegations, or whether and how there is infringement under the doctrine of equivalents. Arthrex will supplement this answer once DePuy Mitek provides this further information. Arthrex further objects to this Interrogatory as premature to the extent that it seeks expert information. Any such information to which DePuy Mitek is entitled will be provided in accordance with the Federal Rules of Civil Procedure and the Joint Case Management Statement filed by the parties and Scheduling Order issued by the Court. Subject to and without waiving its general and specific objections, Arthrex answers:

Arthrex's FiberWire® suture products do not contain any of the "first fiber-forming materials" recited in the claims of the '446 patent, as properly construed. Arthrex further answers that the '446 patent does not have any basic and novel characteristics. See, for example, Arthrex's Response to Interrogatory No. 5, which is incorporated herein by reference. The '446 patent, however, purports to have at least one basic and novel characteristic of the alleged invention in that it claims to achieve certain results with only a combination of one of a listed first fiber-forming material and one of a listed second fiber-forming material. Even if the claims of the '446 patent were improperly construed to support a contention that the Arthrex FiberWire® suture products contain both such fiber-forming materials, Arthrex's FiberWire® suture products have a coating that affects the alleged basic and novel characteristics of the '446 patent and Arthrex's FiberWire® suture products do not achieve the desired results without the coating. Arthrex also answers that at least for these reasons, its FiberWire® suture products do not infringe the claims of the '446 patent under the reverse doctrine of equivalents even if the claims could be construed to cover Arthrex's products.

Arthrex further answers that the function/way/result test is not met since Arthrex's FiberWire® suture products do not perform the same function or achieve the same results as claimed in the '446 patent. Moreover, even if the same function and DSMDB.1884420.1

result were achieved, Arthrex's FiberWire® suture products operate in a manner substantially different than that of the alleged invention defined by the claims of the '446 patent, as properly construed. Moreover, DePuy Mitek would be estopped from contending that there is infringement by the doctrine of equivalents for any limitation that was amended for reasons of patentability. See e.g., Amendment dated August 4, 1993 in which claim 21 was amended from reciting "comprising" to "consisting essentially of." See id. in which specific fiber-forming materials for each set of yarns were added to claim 21.

Arthrex further answers that non-privileged document(s) from which information responsive to this Interrogatory may be derived or ascertained will be produced pursuant to Rule 33(d) of the Federal Rules of Civil Procedure and Rule 33.1 of the Court. Such document(s) will include Arthrex's 510(k) submission to the U.S. Food and Drug Administration as well as various test reports.

# **INTERROGATORY NO. 4.**

Identify (i) when Arthrex first became aware of the Patent-in-Suit, (ii) who, if anyone, at Arthrex decided to market and continue to market the Arthrex's Braided Suture Products in light of Arthrex's knowledge of the Patent-in-Suit; (iii) what opinions (identified by date and author), if any, that person relied on; and (iv) and all other facts that support Arthrex's contention that it has not willfully infringed the Patent-in-Suit.

## **RESPONSE**

Arthrex objects to this Interrogatory as being overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence. The term "Arthrex's Braided Suture Products" as defined by DePuy Mitek, is overly broad and includes products not relevant to the present lawsuit. Arthrex also objects to this DSMDB.1884420.1 10

Interrogatory to the extent that it seeks information or documents protected by the attorney-client privilege, the work product doctrine, and/or any other privilege or immunity. Arthrex further objects to this Interrogatory as premature since Arthrex has not yet decided whether to rely on advice of counsel. Arthrex will supplement its answer to this Interrogatory, as necessary, in accordance with the Joint Case Management Statement and Scheduling Order entered by the Court. Subject to and without waiving its general and specific objections, Arthrex answers:

Arthrex first became aware of the '446 patent in December 2003 when counsel for Arthrex was contacted by counsel for Johnson & Johnson. Arthrex further answers that there was no "decision" to market and continue to market its FiberWire® suture products in light of Arthrex's knowledge of the '446 patent. See also, Responses to Interrogatory Nos. 3 and 5-8, which are incorporated herein by reference.

# **INTERROGATORY NO. 5.**

To the extent that Arthrex contends that any claim of the Hunter patent is invalid under 35 U.S.C. § 102 or 103 (Answer at ¶¶ 9, 10):

- (a) identify each item of prior art upon which Arthrex relies, and make an element-by-element application (providing specific citation to the relevant portions of the prior art) of each allegedly invalid claim to each item of prior art, explaining in detail the grounds for any allegation of invalidity under 35 U.S.C. § 102; and
- (b) state the factual basis for any contention that any claim of the Patent-in-Suit is invalid under 35 U.S.C. § 103, including specifically, Arthrex's contentions of the level of ordinary skill in the art, the similarities and differences between each item of prior art and each claim, the scope and content of the prior art, and any secondary considerations.

#### **RESPONSE**

Arthrex objects to this Interrogatory as being vague and ambiguous to the extent it refers to "the Hunter patent," which is an undefined term. To the extent "the Hunter patent" refers to the '446 patent, Arthrex also objects to this Interrogatory as premature since DePuy Mitek has not yet identified which claim(s) of the '446 patent it is asserting, the basis for its infringement allegations, or whether and how there is infringement under the doctrine of equivalents. Arthrex will supplement this answer once DePuy Mitek provides this further information. Arthrex further objects to this Interrogatory as premature to the extent that it seeks expert information. Any such information to which DePuy Mitek is entitled will be provided in accordance with the Federal Rules of Civil Procedure and the Joint Case Management Statement and the Scheduling Order entered by the Court. Subject to and without waiving its general and specific objections, Arthrex answers:

Non-privileged document(s) from which information responsive to this Interrogatory may be derived or ascertained will be produced pursuant to Rule 33(d) of the Federal Rules of Civil Procedure and Rule 33.1 of the Court. Moreover, U.S. Patents Nos. 5,318,575; 4,610,688; 3,942,532; 5,147,400, as well as others, taken individually and/or when their teachings are combined together or with other known prior art, disclose every limitation of claims of the '446 patent.

#### **INTERROGATORY NO. 6.**

With respect to Arthrex's inequitable conduct defense and counterclaim:

- (a) identify all persons who allegedly committed inequitable conduct;
- (b) state all facts supporting Arthrex's contention that the such persons committed inequitable conduct; and

(c) identify each piece of information that was allegedly withheld and each alleged misrepresentation and why the alleged withheld information or misrepresentation is material.

#### RESPONSE

Arthrex objects to this Interrogatory to the extent that it seeks information not yet in Arthrex's possession. Most of the facts surrounding the alleged inequitable conduct are known to the applicants of U.S. Application No. 838,511 ("the '511 application"), which eventually issued as the '446 patent, and their attorneys; and since discovery has only just begun in this case, Arthrex has not yet had an opportunity to obtain all information responsive to this Interrogatory. Subject to and without waiving its general and specific objections, Arthrex answers:

- At least the applicants of the '511 application and their attorneys, (a) including Hal Brent Woodrow, committed the alleged inequitable conduct.
- (b) During prosecution of the '511 application, the applicants and their attorneys mischaracterized and misrepresented the disclosure of U.S. Patent No. 5,147,400 to Kaplan et al. ("Kaplan") in distinguishing Kaplan from claim 21 of the '511 application. For example, in response to rejections on anticipation and obviousness grounds under 35 U.S.C. §§ 102, 103, on August 4, 1993, the applicants and their attorneys falsely represented that the sheath yarn component of Kaplan always contains at least in part, a bio-absorbable portion and that Kaplan teaches away from a combination of non-bioabsorbable yarns.

The applicants and their attorneys misrepresented Kaplan as stating "in one embodiment, the sheath yarn could also contain a non-bioabsorbable yarn of one or more chemical composition." See Amendment filed August 4, 1993 at page 2. The applicants and their attorneys then immediately went on to state that claim 21 does not claim a sheath yarn composed of a bio-absorbable yarn. *Id*.

Their statements regarding Kaplan's teachings were entirely misleading, however. Kaplan actually states that "sheath component 34 may also be fabricated from individual filaments having more than two different chemical compositions, one or more of which optionally being non-bioabsorbable." [Emphasis added.] Kaplan at column 9, lines 25-28. In other words, Kaplan discloses that the sheath component may be fabricated from individual filaments, all of which may be non-bioabsorbable.

The applicants and their attorney again misrepresented the teachings of Kaplan when they stated that "the sheath, however, may optionally have, in addition to the bioabsorbable sheath yarn, one or more non-bioabsorbable filaments." See Amendment filed August 4, 1993 at page 3. As described above, Kaplan does, in fact, disclose a sheath containing all non-bioabsorbable yarns.

(c) The mischaracterizations and misrepresentations made by the applicants and their attorneys were material since the Examiner ostensibly relied on them in deciding that the rejections based on Kaplan had been overcome and in allowing the '511 application after the Amendment was filed on August 4, 1993.

#### **INTERROGATORY NO. 7.**

With respect to Arthrex's contentions that the asserted claims are invalid under 35 U.S.C. § 112 (Answer at Affirmative defenses ¶11):

- (a) identify each claim of the Patent-in-Suit that is allegedly invalid under 35 U.S.C. § 112; and
- (b) explain the factual basis for each such contention, and identify the specific section and statutory requirement of 35 U.S.C. § 112 that allegedly has not been met.

#### <u>RESPONSE</u>

Arthrex objects to this Interrogatory as premature since DePuy Mitek has not yet identified which claim(s) of the '446 patent it is asserting, the basis for its infringement DSMDB.1884420.1 14

allegations or whether and how there is infringement under the doctrine of equivalents. Arthrex will supplement this answer once DePuy Mitek provides this further information. Arthrex also objects to this Interrogatory to the extent it seeks information within the possession of DePuy Mitek. Subject to and without waiving its general and specific objections, Arthrex answers:

The claims of the '446 patent, if construed to cover Arthrex's FiberWire® suture products, are not enabled by the specification of the '446 patent (§ 112, first paragraph). For example, the '446 patent does not enable one skilled in the art to make and use a surgical suture that requires coating in order to achieve the desired results. The '446 patent also does not enable one skilled in the art to make and use a surgical suture containing ultra high molecular weight polyethylene (UHMWPE) as one of the fiberforming materials. The claims of the '446 patent also do not particularly point out and distinctly claim the subject matter which the applicants regard as their invention (§ 112, second paragraph). For example, the terms "consisting essentially of," "direct intertwining contact" and each of the polymers recited in the claims are indefinite if attempted to be construed in a manner that covers Arthrex's products.

#### **INTERROGATORY NO. 8.**

State all facts that support Arthrex's laches defense (Answer at ¶14) including, but not limited to, what time period constitutes the "delay" alleged in ¶ 14 of Arthrex's Answer; what makes the delay "unreasonable and unjustified" as alleged in ¶ 14 of Arthrex's Answer; and Arthrex's alleged prejudice from the alleged "delay;" and why any such alleged prejudice is material.

#### **RESPONSE**

Arthrex objects to this Interrogatory to the extent that it seeks information not yet in Arthrex's possession. Many of the facts surrounding when DePuy Mitek became DSMDB.1884420.1 15

aware of Arthrex's FiberWire® suture products, and the reasons for DePuy Mitek's delay in filing this lawsuit, are in the possession of DePuy Mitek. Subject to and without waiving its general and specific objections, Arthrex answers:

Arthrex has been selling its FiberWire® suture products since as early as August 2001; more than three years before DePuy Mitek filed this lawsuit. Since Arthrex and DePuy Mitek are competitors, DePuy Mitek knew or reasonably should have known that Arthrex introduced its FiberWire® suture products into the market at that time, yet DePuy Mitek was silent until only recently and further delayed after contacting Arthrex and before filing this lawsuit.

Since its introduction, sales of Arthrex's FiberWire® suture products have grown exponentially. For example, since mid-2001, when only one FiberWire® catalog number was sold, Arthrex's FiberWire® suture products have grown to at least 46 different catalog numbers available for sale. That growth is and was due in large part to the extraordinary efforts made by Arthrex to market, sell and secure quality manufacturing of its FiberWire® suture products. Extensive efforts were made by Arthrex over a substantial period of time without so much as a word of protest from DePuy Mitek.

Arthrex's reliance on DePuy Mitek's silence materially prejudiced Arthrex over the approximately three years of delay inasmuch as Arthrex, relying on DePuy Mitek's silence, negotiated and entered into numerous sales, marketing and manufacturing agreements with third parties in order to initiate and to sustain the growth that FiberWire® has enjoyed.

#### **INTERROGATORY NO. 9.**

Identify each person currently and previously employed by or associated with Arthrex who had or has responsibility for the following:

(a) the design and development of each Arthrex Braided Suture Product; DSMDB.1884420.1 16

- (b) the selection of materials and testing of the suture part of each Arthrex Braided Suture Product;
  - (c) the manufacturing of each Arthrex Braided Suture Product; and
  - (d) the marketing and sales of each Arthrex Braided Suture Product.

#### **RESPONSE**

Arthrex objects to this Interrogatory as being overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence. The term "Arthrex Braided Suture Product," as defined by DePuy Mitek, is overly broad and includes products not relevant to the present lawsuit. Arthrex also objects to this Interrogatory as being vague and ambiguous to the extent it seeks information on persons "associated with" Arthrex. Arthrex further objects to this Interrogatory as overbroad to the extent that it seeks the identity of "each person," in that a host of individuals could have had some responsibility. Arthrex further objects to this Interrogatory to the extent that it seeks information or documents protected by the attorney-client privilege, the work product doctrine, and/or any other privilege or immunity. Arthrex further objects to this Interrogatory to the extent that it seeks information relating to its activities outside of the United States. Subject to and without waiving its general and specific objections, Arthrex answers that the following individuals had substantial responsibility:

- R. Donald Grafton; (a)
- (b) R. Donald Grafton, Anne Waterhouse and Ashley Holloway;
- (c) R. Donald Grafton; and
- (d) R. Donald Grafton.

#### **INTERROGATORY NO. 10.**

With respect to Arthrex's patent misuse defense alleged in ¶ 18 of its Answer explain what Arthrex contends the relevant product and geographic markets are, explain all facts that support any Arthrex contention that DePuy Mitek has or is likely to have market power in the relevant product and geographic markets; and explain all facts that support Arthrex's contention that DePuy Mitek "by virtue of its efforts to obtain, enforce, and use the '446 patent, knowing said patent to be invalid, infringed, and unenforceable, have misused said patent" (Arthrex's Answer at ¶ 18).

#### **RESPONSE**

Arthrex objects to this Interrogatory as premature to the extent that it seeks legal conclusions and expert opinion. Arthrex also objects to this Interrogatory to the extent it seeks information in the possession of DePuy Mitek. Any such information to which DePuy Mitek is entitled will be provided in accordance with the Federal Rules of Civil Procedure and the Joint Case Management Statement filed by the parties. Arthrex further objects to this Interrogatory on grounds that information about relevant product and geographic markets is irrelevant to the defense alleged by Arthrex. Subject to and without waiving its general and specific objections, Arthrex answers:

DePuy Mitek, by virtue of its wrongful enforcement of the '446 patent, which it knows to be invalid and/or not infringed and/or unenforceable, has misused the '446 patent. DePuy Mitek, by virtue of its experience and knowledge, had to know that the '446 patent could not be validly construed to cover any Arthrex product. See also Arthrex's Responses to Interrogatory Nos. 3 and 5-7.

#### **INTERROGATORY NO. 11.**

State whether Arthrex's Braided Suture Products and Convoyed Braided Suture Product have been commercially successful and if so the reasons for their success. DSMDB.1884420.1

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#### **RESPONSE**

Arthrex objects to this Interrogatory as being overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence. The term "Arthrex Braided Suture Products" and "Convoyed Braided Suture Products," as defined by DePuy Mitek, are overly broad and include products not relevant to the present lawsuit. Arthrex also objects to this Interrogatory to the extent that it seeks legal conclusions. Arthrex's FiberWire® suture products do not fall within any claim of the '446 patent and thus, the information sought by this Interrogatory is irrelevant. Arthrex further objects to this Interrogatory as premature to the extent that it seeks expert information. Any such information to which DePuy Mitek is entitled will be provided in accordance with the Federal Rules of Civil Procedure and the Joint Case Management Statement and Scheduling Order entered by the Court. Subject to and without waiving its general and specific objections, Arthrex answers:

Arthrex considers its FiberWire® suture products to be successful. Reasons for this success include the fact that they are coated suture products with increased tieability, pliability and handling characteristics as well as other advantages over other commercially available suture products.

#### **INTERROGATORY NO. 12.**

Identify each product (by trade name, manufacturer or seller, and other identifying information) that competes with Arthrex's Braided Suture Products and Convoyed Braided Suture Products and in what product and geographic markets each product competes with Arthrex's Braided Suture Products and Convoyed Braided Suture Products.

#### **RESPONSE**

Arthrex objects to this Interrogatory as being overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence. The term "Arthrex's Braided Suture Products" and "Convoyed Braided Suture Products," as defined by DePuy Mitek, are overly broad and include products not relevant to the present lawsuit. Arthrex also objects to this Interrogatory to the extent that it seeks legal conclusion. Arthrex further objects to this Interrogatory as premature to the extent that it seeks expert information. Any such information to which DePuy Mitek is entitled will be provided in accordance with the Federal Rules of Civil Procedure and the Joint Case Management Statement and Scheduling Order entered by the Court. Arthrex also objects to this Interrogatory on the grounds that information about relevant product and geographic markets is irrelevant. Subject to and without waiving its general and specific objections, Arthrex answers:

Commercially available products that principally compete with Arthrex's FiberWire® suture products include Orthocord, Maxbraid, Herculine, Ethibond, Tevdek, Merciline Tape and Force Fiber.

#### **INTERROGATORY NO. 13.**

Identify any product that Arthrex contends is a non-infringing substitute and explain when any alleged non-infringing substitute was readily available to Arthrex, and explain all efforts required to switch from each Arthrex Braided Suture Product to any alleged readily available non-infringing substitute.

#### RESPONSE

Arthrex objects to this Interrogatory as being overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence. The term "Arthrex Braided Suture Product" as defined by DePuy Mitek, is overly broad and DSMDB.1884420.1 20

includes products not relevant to the present lawsuit. Arthrex also objects to this Interrogatory to the extent that it seeks legal conclusion. Arthrex further objects to this Interrogatory to the extent that it seeks information or documents protected by the attorney-client privilege, the work product doctrine, and/or any other privilege or immunity. Arthrex also objects to this Interrogatory as premature to the extent that it seeks expert information. Any such information to which DePuy Mitek is entitled will be provided in accordance with the Federal Rules of Civil Procedure and the Joint Case Management Statement and Scheduling Order entered by the Court. Arthrex further objects to this Interrogatory because DePuy Mitek's assertion of non-infringing substitutes is vague and indefinite. Subject to and without waiving its general and specific objections, Arthrex answers:

Arthrex's FiberWire® suture products do not infringe any claim of the '446 patent and thus, there is no reason for Arthrex to switch. See also Response to Interrogatory No. 12, which is incorporated herein by reference.

# **INTERROGATORY NO. 14.**

Identify each person whom Arthrex expects to call at trial or at the Markman hearing, including but not limited to expert witnesses, and state the qualifications of all persons listed, the subject matter, and the substance of the facts and opinions to which each person is expected to testify.

#### **RESPONSE**

Arthrex objects to this Interrogatory as premature to the extent it seeks the identity of expert information and any such information to which DePuy Mitek is entitled will be provided in accordance with the Federal Rules of Civil Procedure and the Joint Case Management Statement and Scheduling Order entered by the Court.

Dated: February 16, 2005

As to the Objections,

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Counsel for Defendant

Arthrex, Inc.

# **CERTIFICATION**

I, John W. Schmieding, state that I have been authorized by Defendant Arthrex, Inc. to execute these Answers to DePuy Mitek, Inc.'s First Set of Interrogatories, and declare, under penalty of perjury that, based upon my knowledge, information and belief, the statements provided herein are true and correct.

Date: 7/16/05

John W. Schmieding

# **CERTIFICATE OF SERVICE**

It is hereby certified that a true and correct copy of the foregoing Arthrex, Inc.'s Objections and Answers to DePuy Mitek, Inc.'s First Set of Interrogatories and Certification have been served by Fedex overnight delivery on the following counsel for DePuy Mitek, Inc. on this 16th day of February 2005:

Lynn A. Malinoski Woodcock Washburn, LLP One Liberty Place, 46th Floor Philadelphia, PA. 19103

Daniel J. Gleason Nutter McClennan & Fish LLP World Trade Center West 155 Seaport Boulevard Boston, MA 02210-2604

# IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc. a Massachusetts Corporation Plaintiff,	) ) )
,	) )
V.	) CIVII ACHOIT NO. 04-12437 1 133
Arthrex, Inc. a Delaware Corporation	) ) )
Defendant.	ý )

# RESPONSIVE EXPERT REPORT OF DR. DEBI PRASAD MUKHERJEE CONCERNING NON-INFRINGEMENT OF U.S. PATENT NO. 5,314,446 AND OTHER MATTERS

Pursuant to the provisions of Rule 26(a)(2) of the Federal Rules of Civil

Procedure, the Joint Case Management Statement adopted by the Court on February 18,

2005, and agreement between the parties, the undersigned, Dr. Debi Prasad Mukherjee,
an expert witness for Defendants Arthrex, Inc. and Pearsalls, Limited (together,

"Defendants") hereby sets forth his responsive expert report concerning noninfringement and other matters as follows.

# I. INTRODUCTION

I have been retained, through Dickstein Shapiro Morin & Oshinsky LLP, as a technical expert by Arthrex, Inc. ("Arthrex") and Pearsalls, Ltd. ("Pearsalls") (together "Defendants") to review U.S. Patent No. 5,314,446 ("the '446 patent"), its prosecution history, the Expert Report of Dr. David Brookstein ("Brookstein Report"), reports prepared by the Center for Tribology, Inc., as well as by Dr. Robert Burks, and certain other materials, and to provide my opinion on issues raised by Dr. Brookstein's report, including: i) whether a person of ordinary skill in the art in February 1992 would have understood the term "PE," as described and claimed in the '446 patent, to include ultra high molecular weight polyethylene ("UHMWPE"); ii) what a person of ordinary skill in the art in February 1992 would have understood to be the basic and novel characteristics of the invention described and claimed in the '446 patent; iii) whether the addition of a coating, as used on Arthrex's FiberWire sutures, affects those basic and novel characteristics; iv) whether the addition of nylon, as used in Arthrex's TigerWire sutures, affects those basic and novel characteristics; v) whether the addition of an adhesive, as used on Arthrex's FiberStick sutures, affects those basic and novel characteristics, vi) whether the braids produced by Pearsalls are suitable for uses other than FiberWire suture; and vii) whether claim 9 of the '446 patent, which I understand has been newly asserted by DePuy Mitek, is invalid in view of prior art. I am being compensated at a rate of \$1000.00 per day.

I expect to be called to provide expert testimony at trial regarding opinions formed resulting from my investigation of these issues, any matters set forth in this report, and rebuttal of any matters raised by Plaintiff DePuy Mitek. This report includes my opinions regarding these matters. I specifically reserve the right to formulate and offer additional opinions based on any other reports received from DePuy Mitek, or on any additional information that may be provided, and I likewise reserve the right to supplement my opinions based on future court rulings, agreements between the parties, and additional evidence submitted by either party prior to or during trial. Opinions formed are covered below in Section VI. Documents reviewed and considered are identified in Section III and Ex. 1.

# II. SUMMARY OF MY OPINIONS

Based upon my review and consideration of the materials identified in Ex. 1, it is my opinion that a person of ordinary skill in the art, in February 1992, would not understand the term "PE," as described and claimed in the '446 patent, to include UHMWPE.

It is also my opinion that a person of ordinary skill in the art, in February 1992, would have understood the basic and novel characteristics of the invention described and claimed in the '446 patent to be a suture having two dissimilar yarns braided together to achieve improved handleability and pliability performance without significantly sacrificing its physical properties.

It is further my opinion that the addition of a coating, as used on Arthrex's FiberWire suture, affects the basic and novel characteristics of the invention described and claimed in the '446 patent. It is also my opinion that the addition of nylon, as used in Arthrex's TigerWire suture, affects the basic and novel characteristics of the invention described and claimed in the '446 patent. And it is my opinion that the addition of an adhesive, as used on Arthrex's FiberStick suture, affects the basic and novel characteristics of the invention described and claimed in the '446 patent.

It is also my opinion that the unsterilized and untipped braids of the type manufactured by Pearsalls are suitable for uses other than as FiberWire suture. For example, the same braids are suitable for use as fishing line.

It is further my opinion that U.S. Patent No. 4,610,688, ("the '688 patent"), when combined with U.S. Patent No. 5,120,802 ("the '802 patent"), and/or the general teachings of the art, includes every limitation of newly asserted claim 9 of the '446 patent. It is also my opinion that in the event that the Court were to determine that UHMWPE does fall within the meaning of PE, as described and claimed in the '446 patent, then the '575 patent includes every limitation of newly asserted claim 9 of the '446 patent. Further, if the Court does include UHMWPE within the meaning of PE, then it is also my opinion that the combination of UK Patent Application No. 2,218,312A to Burgess ("the Burgess application") and i) Cohan, et al., *An Evaluation of Ultrastrong Polyethylene Fiber as an Ophthalmic Suture*, Arch Ophthalmol – Vol. 103, December 1985

("the Cohan article"); ii) *Dyneema SK60, High strength/ high modulus fiber, Properties & Applications* ("the DSM brochure"); and/or iii) either one of U.S. Patent Nos. 4,563,392 or 4,543,286, both to Harpell et al. ("the Harpell patents"), would include every limitation of newly asserted claim 9 of the '446 patent.

#### III. REVIEW AND USE OF DOCUMENTS AND OTHER MATERIALS

The documents and things I have reviewed and considered in the preparation of this report are the '446 patent, its prosecution history, the Expert Report of Dr. David Brookstein, reports prepared by the Center for Tribology, Inc., as well as by Dr. Robert Burks, Arthrex's Responses to DePuy Mitek's Interrogatories, DePuy Mitek's Responses to Arthrex's Interrogatories, U.S. Patents Nos. 5,318,575, 4,610,688 and 5,120,802, the Burgess application, the Cohan article, the DSM brochure, the Harpell patents, various documents of DePuy Mitek, Ethicon, Arthrex and Pearsalls, and the documents and things identified at Ex. 1. I have also relied upon my experience and well-known principles in the manufacturing and processing fields of fibers that can be used for biomedical applications, and discussions with Bill Benavitz of Arthrex, Norman Gitis of the Center for Tribology, Inc. and John Witherspoon, who I understand is a legal expert retained in this case.

# IV. QUALIFICATIONS

My qualifications as an expert witness are listed in my Curriculum Vitae attached as Ex. 2.

# V. THE '446 PATENT AND PROSECUTION HISTORY

While my first report included a section discussing the specification and the prosecution history of the '446 patent, I believe it is helpful to repeat it, as necessary, in this report, together with other information, to the extent it is relevant to my opinions in this report.

The '446 patent is directed to heterogeneous braids that can be used as a component of either surgical suture or ligatures. Ex. 3 at col. 1, ll. 6-7. The '446 patent describes the benefits of a braided multifilament over a monofilament. Some of those benefits include enhanced pliability, knot security and tensile strength when compared with a monofilament. Ex. 3 at col. 1, ll. 8-10. As the '446 patent describes, the enhanced pliability of a braided multifilament results from the lower resistance to bending of a bundle of very fine filaments relative to one large diameter monofilament.

The '446 patent then describes that although an improvement over monofilaments, braided multifilaments still often presented certain problems when coated.

The '446 patent then goes on to describe that the prior art attempts to improve braid properties have overlooked the importance of fiber-fiber friction and its impact on braid properties. The specification suggests the use of braided multifilaments made of fibers composed of highly lubricious polymers as a solution. The specification explains

that while such braids will be highly pliable, they will also be relatively weak and unusable for most suture applications. Ex. 3 at col. 2, ll. 22-25.

The proposed solution described in the '446 patent is a heterogeneous braid made up of two dissimilar materials. According to the specification, the braid is made up of a first fiber-forming material mechanically interlocked or weaved with a second fiber-forming material. The specification also states that the first fiber-forming material is a lubricious material, and that the second fiber-forming material is added for strength. The fact that the first fiber-forming materials are lubricious but too weak for most suture applications is further made clear by the specification which states that "a volume fraction [of lubricating yarns] above about 80% may adversely affect the overall strength of the braid." As described throughout the specification, there is a tradeoff between the properties of the two materials – one being lubricious but weak, the other being added for strength. The specification further recognizes that gains in handleability/pliability outweigh any loss of strength.

The specification also repeatedly states that the advantage of the above-described braid construction is that the braid exhibits improved handleability and pliability without appreciably sacrificing its physical properties. Ex. 3 at col. 2, ll. 32 - 37; ll. 62 - 66; col. 6, ll. 7 - 8.

Claim 1 of the '446 patent is to a surgical suture, the surgical suture consisting essentially of a heterogeneous braid composed of a first and second set of continuous

and discrete yarns in a sterilized and braided construction. Claim 1 also states that at least one yarn from the first set is in direct intertwining contact with a yarn from the second set. Claim 1 also states that each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material and that each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material. Claim 1 further defines the first fiber-forming materials as one of PTFE, FEP, PFA, PVDF, PETFE, PP and PE, and further defines the second fiber-forming materials as one of PET, nylon and aramid. The other claims that are asserted add additional limitations.

The application for the '446 patent was filed on February 19, 1992, as U.S. Patent Application No. 07/838,511 ("the '511 application"). At the time the '511 application was filed, four inventors were listed – Alastair W. Hunter, Arthur Taylor, Jr., Mark Steckel and Dennis D. Jamiolkowski.

During prosecution of the '511 application, the patent examiner at the U.S. Patent and Trademark Office ("PTO") issued a restriction requirement on July 8, 1992. I understand from Defendants' legal expert that a restriction requirement is issued when the examiner believes that a patent application contains at least two different inventions (e.g., in the case of the '446 patent, a heterogeneous braid and a surgical suture). The applicants must then select one invention which remains in the application.

In issuing the restriction requirement, the patent examiner asserted that the '511 application contained two different inventions – i) a heterogeneous braid and ii) a

surgical suture, and that the applicants were required to select one of those two inventions which would remain in the '511 application. The examiner also stated that the heterogeneous braid invention was "an intermediate product [that] is useful to make other than the final product [of a surgical suture]." The examiner then stated that the heterogeneous braid invention was "deemed to be useful as a fishing line." Ex. 4 at 2. The applicants selected the surgical suture inventions (i.e., claims 21-24).

Further, during prosecution of the '511 application, the patent examiner at the U.S. Patent and Trademark Office ("PTO") cited the Burgess patent application and rejected the then-pending claims (i.e., claims 21-24). The Burgess patent application disclosed a heterogeneous braided fishing line comprised of two dissimilar materials – DYNEEMA (which is a brand name for UHMWPE) and polyester and/or nylon. Ex. 4 at 1-2.

The examiner found that the Burgess application disclosed a braided fishing line made up of two polymers with different properties, and therefore, it was "known to braid filaments of two dissimilar polymers together to form a structure which embodies the desirable properties of each fiber." Ex. 4 at 4. Thus, it was known to make this type of braid for these purposes. The examiner reasoned that it would have been obvious to a person of ordinary skill in the art at the time to use a heterogeneous braid for a suture since: i) braided sutures were, at the time, well known in the art; ii) many of the requirements of sutures were comparable to those of fishing line – strength, low

stretchability, etc.; and iii) many of the same materials were used to make both fishing lines and sutures. Ex. 4 at 5.

In response to the rejection based on the Burgess application, Ethicon's attorney recognized that UHMWPE had great strength properties, but argued that it would be bad to use UHMWPE for a suture because it has low elongation and poor knot strength properties. The Ethicon attorney also asserted that if a medical designer were to actually build a surgical suture using the braided combination of UHMWPE and polyester and/or nylon – the combination disclosed in the Burgess application - then "he would inevitably design an unacceptable suture," (Ex. 5 at 3-4) and that the braided combination disclosed in the Burgess application would have "poor knot strength properties." Ex. 5 at 2-3. The '511 application eventually issued as the '446 patent.

# VI. OPINIONS

A. "PE" as described and claimed in the '446 patent does not include UHMWPE

I understand from my discussions with John Witherspoon that the Court will ultimately interpret the meaning of the claim language. In order to assist the Court with interpreting the claim language, I am providing in this section of my report an explanation of why I believe the '446 patent does not include UHMWPE and why a person of ordinary skill in the art would not understand the term "PE," as it is described and claimed in the '446 patent to include UHMWPE. As I mentioned in my first report, it is my opinion that a person of ordinary skill in the art, in February 1992,

had an undergraduate degree in engineering or science and several years (e.g., approximately 3-5) experience with manufacturing and/or processing of fibers and sutures which can be used for biomedical applications.

It is my opinion that a person of ordinary skill in the art would not understand that the term "PE," as described and claimed in the '446 patent, includes UHMWPE.

The reasons for my opinion include the same reasons I previously mentioned as to why I believe the '446 patent specification does not reasonably convey to one of ordinary skill in the art that the inventors had possession of UHMWPE.

I add some additional comments. It is my understanding, from the legal expert, that the prosecution history of a patent plays a role during the claim construction process. I have reviewed the prosecution history of the '511 application and it is my opinion that a person of ordinary skill in the art would understand that the applicants argued that UHMWPE was *not* part of their invention.

As I described above, in response to the patent examiner citing the Burgess application in rejecting claims 21-24, Ethicon's attorney argued that it would be bad to use UHMWPE for a suture because it has low elongation and poor knot strength properties. The Ethicon attorney also asserted that if a medical designer were to actually build a surgical suture using the braided combination of UHMWPE and polyester and/or nylon – the combination disclosed in the Burgess application – the braid would have "poor knot strength properties." (Ex. 5 at 2, 3) and "he would

inevitably design an unacceptable suture." Ex. 5 at 3-4. It is my opinion that a person of ordinary skill in the art reading these remarks made by Ethicon's attorney would clearly understand that it was Ethicon's position that UHMWPE is *not* part of the invention of the '446 patent.

Another reason why I believe UHMWPE is not included within the meaning of "PE" as it is described and claimed in the '446 patent is because there is no mention at all within the '446 patent that "PE" can be used to impart strength to the braid. It was known at the time that UHMWPE was an extremely strong material, and as I explained in my previous report, there were several suggestions to use UHMWPE for suture because of its strength component. The evidence in this case shows that Ethicon and the inventors knew that UHMWPE has great strength. The Ethicon attorney, when responding to the Burgess rejection, specifically states that UHMWPE "has great strength properties." In addition, Dr. Steckel testified that during the development work that lead to the '446 patent he knew that UHMWPE had great strength. Ex. 6 at 190:18-21. If the inventors intended for the described "PE" to include UHMWPE, one would expect that they would have specifically mentioned "PE" as a material that can be used to impart strength to the suture. Yet there is absolutely no mention of "PE" when the patent discusses materials that add strength to the suture. The absence of any such discussion, particularly in light of Ethicon's knowledge, would strongly suggest to a person of ordinary skill in the art that the inventors did not mean to convey that UHMWPE fell within the meaning of "PE."

I see that Dr. Brookstein assumed that the meaning of "PE" within the '446 patent includes UHMWPE. Brookstein Report at 9. For the reasons I describe above, it is my opinion that this is an incorrect assumption.

I have also read DePuy Mitek's third supplemental response to Arthrex's Interrogatory No. 2. I understand that DePuy Mitek has asserted that Arthrex's statements regarding the meaning of "PE" within the context of the '446 patent are "wrong" and that "Arthrex's citations are to certain preferred embodiments." I disagree.

It is my opinion that a person of ordinary skill in the art reviewing, for example, the background portion of the '446 patent specification would understand that the discussion is not limited to a preferred embodiment when it describes that "braids of highly lubricious polymers" will be highly pliable but they will also be relatively weak and unusable for most suture applications. Ex. 3 at col. 2, Il. 22-25. This general description of highly lubricious polymers is consistent with what was known in the art about general purpose PE and inconsistent with what was known in the art about UHMWPE. It is also my opinion that the specification is generally describing lubricious polymers where it states "a volume fraction of *lubricating yarns* below about 20 percent will not typically improve the pliability of the braid, and a volume fraction above about

80 percent may adversely affect the overall strength of the braid." Ex. 3 at col. 4, ll. 52-54. [Emphasis added.] The entirety of the discussion in the patent specification explains that there is a tradeoff between the two fiber-forming materials – lubricious but weak versus strong. The point made by the inventors is that gains in pliability and handleability by using the combination of lubricious, but weak materials with a stronger material outweighs the loss of suture strength resulting from combining a weaker lubricious material with the stronger material. These observations in the specification go far beyond the "preferred embodiment."

B. There is a substantial difference between UHMWPE and the first fiberforming materials of claim 1 of the '446 patent

I understand that Dr. Brookstein contends that if UHMWPE is not included within the meaning of "PE" of claim 1 of the '446 patent, and there is no literal infringement, then there is infringement under the doctrine of equivalents. I have been informed by the legal expert that in order for infringement to be found under the doctrine of equivalents, the difference between the claim limitation and the alleged "equivalent" portion of the accused product must be insubstantial. For the reasons described below, it is my opinion that the difference between UHMWPE and any of the first fiber-forming materials of claim 1 of the '446 patent is substantial.

For example, as I stated in my first report, the '446 patent describes that the braid is made up of a first fiber-forming material mechanically interlocked or weaved with a second fiber-forming material. The materials described as first fiber-forming materials

are PTFE, FEP, PFA, PVDF, PETFE, PP and PE. The materials described as second fiberforming materials are PET, nylon and aramid.

The specification also states that the first fiber-forming materials are lubricious materials that act as lubricating yarns to improve the overall pliability and handling characteristics of the braid. The specification explains that these lubricious materials are too weak to be used alone for most suture applications, and therefore, the second fiber-forming materials are added to improve the overall strength of the braid.

The description in the specification of the first fiber-forming materials is very different from UHMWPE. Unlike the first fiber-forming materials, which are described as being lubricious but relatively weak, UHMWPE is a well-known, highly specialized fiber material with strength properties that are far superior to those of any of the first fiber-forming materials of claim 1, including general purpose PE. Thus, it is my opinion that the difference between UHMWPE and the first fiber-forming materials is substantial.

In addition, while the specification describes that the second fiber-forming materials of claim 1 of the '446 patent are added for strength, it is the UHMWPE that is added to Arthrex's FiberWire suture for increasing its strength. Even Dr. Brookstein recognizes that fact. Brookstein Report at ¶ 63. This is the exact opposite of what the '446 patent describes. I find this to be another substantial difference.

Further, when Arthrex and Pearsalls developed the FiberWire suture, Arthrex created an entirely new category of medical products called high-strength suture. Prior to FiberWire, there was no such product on the market. It is the UHMWPE that makes FiberWire so strong. As I previously mentioned, there is no indication at all within the '446 patent that a high-strength suture was even contemplated by the inventors. To the contrary, the inventors had conceded the fact that there was a tradeoff necessary in having a suture that had better handleability and pliability – that tradeoff was lower strength. That is why the specification repeatedly states that the object of the invention is to achieve better handleability and pliability without appreciably sacrificing physical characteristics, including most specifically, strength. Nowhere is there any description or teaching within the '446 patent that the resulting suture will have strength that is far superior to the prior art sutures identified in the patent. In my opinion, this is another substantial difference.

Putting it in terms of the function/way/result test, as did Dr. Brookstein, it is my opinion that the difference between the function performed by the UHMWPE in FiberWire is very different than that of the first fiber-forming materials of claim 1 of the '446 patent. As I stated above, the function performed by UHMWPE in FiberWire is to impart tremendous strength to the FiberWire suture, whereas the function performed by the first fiber-forming materials is to add lubricity with the recognition that these materials will detract from the strength of the resulting suture. For these same reasons,

it is also my opinion that the way in which the UHMWPE performs in Arthrex's FiberWire suture is substantially different from the way in which the first fiber-forming materials perform in the suture of claim 1 of the '446 patent.

It is further my opinion that the result obtained by substituting UHMWPE for the first fiber-forming materials is substantially different. As I stated earlier, when Arthrex and Pearsalls developed FiberWire, Arthrex introduced the first high-strength suture into the marketplace. There is no indication within the '446 patent that such a high-strength suture was contemplated. If it were, one would expect it to be mentioned in the specification, especially since such a suture would be far superior to any suture that was known at the time, at least for the orthopedic applications for which FiberWire is used. Since the use of UHMWPE to impart strength results is a very different suture than that contemplated by using the first fiber-forming materials of the '446 patent, this is another substantial difference.

Dr. Brookstein appears to state that as long as a material used for the first set of yarns contributes a property that is different than a yarn from the second set, that material is equivalent to the "first fiber-forming material" of claim 1 of the '446 patent. Brookstein Report at 20-23. It is my opinion that this can not be true since it would mean that any suture having two different materials braided together in direct intertwining contact would fall within the claims of the '446 patent. As I understand it, the PTO examiner rejected a claim this broad. Ex. 4 at 4.

C. UHMWPE is used in FiberWire to impart strength and PET is used in FiberWire to improve handleability

As I previously mentioned, the specification of the '446 patent describes that the first fiber-forming materials are added to improve suture handleability and that such materials are too weak for most suture applications. It is the second fiber-forming materials that are added for increased strength. The way in which the individual materials act in FiberWire is the opposite. UHMWPE that is added for strength and the PET is added to improve knot tying – a well-known handleability characteristic.

D. The basic and novel characteristics described in the '446 patent are a suture having two dissimilar yarns braided together to achieve improved handleability and pliability performance without significantly sacrificing its physical properties

I have been asked to provide my opinion regarding what a person of ordinary skill in the art in February 1992 would understand to be the basic and novel characteristics described in the '446 patent. It is my opinion that a person of ordinary skill in the art, in February 1992, reading the specification of the '446 patent would understand the basic and novel characteristics to be a suture having two dissimilar yarns braided together to achieve improved handleability and pliability performance without significantly sacrificing its physical properties. This concept is repeated throughout the specification. Ex. 3 at col. 2, ll. 32 - 37; ll. 62 - 66; col. 6, ll. 7 - 8.

The specification also describes that there is a tradeoff between the two fiberforming materials that make up the two dissimilar yarns – one being lubricious, but weak, the other being strong. The tradeoff is that the gains achieved in pliability and handleability by using the combination outweighs the loss of suture strength resulting from combining a weaker lubricious material with the stronger material. According to the specification, the resulting suture is one with improved handleability and pliability performance without significantly sacrificing its physical properties.

The '446 patent specifically refers to "pliability" in connection with "resistance to bending," (Ex. 3 at col. 1, ll. 11-15, l. 24) and "bending rigidity," (Ex. 3 at col. 6, ll. 44-45, col. 8, Table, ll. 44-46), which are the inverse of pliability.

One handleability characteristic specifically identified in the patent is "knot tie down." Ex. 3 at col. 6, II. 7-8. Knot tie-down is a well-known suture handleability characteristic intended to be a measure, which can be either objective or subjective, of the ability of a knot formed in the suture to slide down the suture. Some other factors that can be measured which indirectly relate to knot tie-down include braid chatter (i.e., the smoothness of the braid) and the coefficient of friction (another objective measure of smoothness) of the braid surface.

With regard to knot tie-down, the specification states that while a coating can be added "to further improve the handleability and knot tiedown performance of the braid" (Ex. 3 at col. 6, ll. 5-8) [emphasis added], it also states that if the surface of the braid contains "a significant fraction of the lubricious yarn system, the . . . coating may be eliminated." Ex. 3 at col. 6, ll. 13-17. In other words, it is my opinion that the '446

patent is telling a person of ordinary skill in the art that the handleability (e.g, knot tiedown performance) is enhanced due to the braided construction of two dissimilar materials braided together, indeed improved so much in certain configurations that the need for coating can be eliminated.

In addition to pliability and knot tie-down, there are other suture handleability characteristics that were well known in the art at the time of the invention, and therefore, would be understood by a person of ordinary skill in the art to be included in improved handleability, as it is used in the '446 patent. They include tactile feel, compliance, tissue drag, knot security, knot stability, coefficient of friction, stiffness, softness, smoothness, lack of chatter, tissue abrasion and lie-down of the knot. The specification specifically or implicitly mentions some of these (e.g., knot security, knot stability, compliance, stiffness, coefficient of friction, lack of chatter). The others were well known in the suture art at the time of the invention and they were also recognized as such by Ethicon as well. I have reviewed Ethicon documents specifically mentioning these suture handleability characteristics, including documents during the development that lead to the '446 patent. Ex. 7. Mr. Jamiolkowski, one of the original inventors, also confirmed that suture handling properties includes knot tie-down, tactile feel (or hand), pliability, knot security and chatter. Ex. 8 at 140:5-24; 165:16-166:3. Dr. Steckel, another inventor, also confirmed that suture handling is "the ease of manipulation by the surgeon," with handling properties including "pliability, its roughness, smoothness,

and its frictional properties against itself," and also including chatter and knot tiedown. Ex. 6 at 77:3-78:2; 79:19-23.

The '446 patent describes the "physical properties" of the braid in terms of tensile strength and knot strength. Ex. 3 at col. 2. l. 66; col. 8, ll. 19-21, Table. Knot security is also mentioned as a property that is not sacrificed with improvements in pliability and handling properties. Ex. 3 at col. 2, ll. 66. Knot security provides an indication as to the number of throws required to secure a knot so that it fails to slip before cleanly breaking. Ex. 3 at col. 6, ll. 36-39.

I have reviewed Dr. Brookstein's report and I understand that he has been asked to assume that "the basic and novel characteristics [of the invention] are a heterogeneous braid of dissimilar non-bioabsorbable yarns of the type claimed, where at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, and the dissimilar yarns have at least some different properties that contribute to the overall properties of the braid." Brookstein Report at 9.

I disagree with that assumption for the reasons stated above. In addition, Dr. Brookstein's report ignores much of what is taught in the specification. For example, while the specification does disclose direct intertwining contact between two dissimilar yarns, the '446 patent specification also discloses that the desired, novel result of this construction is a suture with better handleability and pliability performance without significantly sacrificing its physical properties. This is also consistent with Mr.

Jamiolkowski's statements. Ex. 8 at 163:11-20. Therefore, I believe Dr. Brookstein's assumption regarding the invention is inaccurate.

- E. The coating added to Arthrex's FiberWire suture materially affects the pliability, handleability and physical properties of FiberWire
  - 1. Coating materially affects suture handleability

It is my opinion that a person of ordinary skill in the art in February 1992 would understand the '446 patent to be teaching that coating materially affects suture handleability, including knot tiedown. For example, the '446 patent specification itself recognizes coating's effect on these properties where it states that coating the heterogeneous braid will "further improve the handleability and knot tiedown performance of the braid." Ex. 3 at col. 6, ll. 5-8.

Further, it was widely known and undisputed in the suture art in February 1992 that coating materially affects suture handling properties, including knot tie-down, and pliability. For example, there are many patents, including many Ethicon patents, that describe how coating affects these specific handling properties of suture. See, e.g., Ex. 9 at Abstract, col. 1, ll. 14-18; Ex. 10 at col. 1, ll. 11-15; Ex. 11 at col. 1, ll. 8-12; Ex. 12 at col. 1, ll. 12-15. There are also many articles on the subject as well. See, e.g., Ex. 13 at 525. I have also reviewed Ethicon documents stating the same thing. For example, in connection with the development of Ethicon's Panacryl suture, Ethicon stated that "the purpose of coating the Panacryl braided suture is to provide the suture with good

handling properties . . . such as knot slide, suture roughness, and knot security." Ex. 14 at 1.

This is also consistent with DePuy Mitek documents I have reviewed, all of which confirm that coating affects suture handling properties. Ex. 15 at 2. I have also reviewed Arthrex documents that also state that coating on the FiberWire product affects specific handling properties. For example, the directions for use (DFU) for FiberWire states that the coating acts as a lubricant for suture sliding, knot tying and ease of passing suture through tissue. Ex. 16. Dr. Steckel, one of the inventors of the '446 patent, also stated during his deposition that the reason why people coat sutures is to improve handleability and knot tie-down. Ex. 6 at 296:3-7.

It is also generally known in the suture art that coating materially affects a suture's tactile feel or smoothness. Ex 10 at col. 1. ll. 11-12. This is a subjective test usually performed by a surgeon in which the surgeon runs the suture through his hands and qualitatively evaluates its "feel." Sometimes, the surgeon attaches a quantitative value to the tactile feel of the suture so that it can be compared relative to other coated or uncoated sutures. I have reviewed Ethicon documents in which a tactile feel test is performed in evaluating different coating type and concentrations. Ex. 17 at Table 24.

Further, it is generally understood in the suture art that coating materially affects how easily a suture passes through tissue – commonly known as "tissue drag." The

effects of coating on tissue drag are described in Ethicon patents (Ex. 10 at col. 1, ll. 11-15) as well as other Ethicon documents. Ex. 18 at 11.

It was also generally understood in the suture art in February 1992 that coating materially affects suture pliability/bendability. It was known that adding coating to a suture could either improve pliability/bendability or adversely affect pliability/bendability. See Ex. 9 at col. 1, ll. 14-18; see also Ex 3 at col. 1, 20-22; col. 6, ll. 15-17.

I have also reviewed tests that show that the coating on FiberWire materially affects various handleability or pliability characteristics. In addition, I have reviewed results of a test entitled "Knot Tiedown" dated February 16, 2004 (Ex. 19). I understand the test was conducted by Arthrex and was intended to objectively show how coating affects knot tiedown.

The objective of the test was to simulate a surgeon's half-hitch knot and to determine the amount of force required to initiate movement of the knot down the line of suture – much like a surgeon moves the knot down the line of suture toward the wound. The test was conducted on both coated and uncoated samples of Arthrex's US No. 2 FiberWire suture. The test results for the two sutures were very different. By this test, Arthrex demonstrated that when coating is added to FiberWire suture, it becomes

approximately 2-1/2 times easier to slide the knot down the suture.<sup>1</sup> In my opinion, these results demonstrate that coating materially affects knot tiedown of FiberWire suture.

In addition to the above described test, I have suggested tests of my own on coated and uncoated samples of FiberWire suture. Like the Arthrex test, the tests I suggested were objective in nature and also demonstrate that coating materially affects the handleability or pliability characteristics of FiberWire suture. The tests were conducted by the Center for Tribology in Campbell, California ("CETR"). The results are attached as Ex. 20. I understand that many of the world's leading suture manufacturing companies – including Ethicon and U.S. Surgical Corp. – use CETR to conduct various tests on their own suture.

Specifically, the tests conclusively show that the knot tie-down, chatter, coefficient of friction, knot security, pliability and tissue drag characteristics of FiberWire are each materially affected by the addition of coating. For example, the knot tie-down (knot run-down) test measures the force required to initiate movement of a half-hitch knot formed on the suture and also the force required to slide the knot down the suture. The results of the knot tie-down test are a function of the smoothness of the surface of the braid. The results of the knot tie-down test performed by CETR

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The mean peak force required to initiate slippage of the knot on the uncoated suture was 32.0N, whereas only 12.7N were required to initiate slippage of the knot on the coated suture.

demonstrate that approximately 1.8 times as much force was required to slide the knot on the uncoated FiberWire suture as compared with the coated FiberWire suture. Ex. 20 at 7-8.

The chatter and coefficient of friction tests are also measures of the smoothness of the braid surface and are also directly related to the knot tie-down test in that way. The more smooth the surface of the braid, the less force that is required to move the knot along the surface of the suture – this is a very desirable feature for surgeons working with surgical suture. Additionally, the more smooth the surface of the braid, the less chatter the knot will experience as it travels along the surface of the braid. The coating added to FiberWire smoothens out the "peaks" and "valleys" formed on the surface of the braid. As those peaks and valleys are smoothened, it becomes easier for the knot to move along the surface of the suture (i.e., less force is require to move the knot along the suture). The results of the coefficient of friction and chatter tests conducted by CETR are consistent with the knot tie-down test results. Specifically, the coefficient of friction for the uncoated FiberWire suture was approximately 1.8 times higher than that of the coated FiberWire suture. The chatter tests showed a similar differential between coated and uncoated FiberWire suture.

CETR's test results also show that the addition of coating to FiberWire suture improves the suture's pliability/bendability. Specifically, there was an approximately 63% difference in pliability/bendability for the coated and uncoated FiberWire samples,

demonstrating that the coating materially affects FiberWire's pliability/bendability. Ex. 20 at 3-4.

In addition, I conducted my own subjective "drape test" on samples of coated and uncoated FiberWire suture to determine the coating's effect on the pliability of the suture. The drape test involves draping the suture over my extended index finger and observing the degree to which the suture conforms to the shape of my finger. The results of my test showed that the coated FiberWire suture conformed to the shape of my index finger to a much greater degree than did the uncoated FiberWire suture, confirming that the coating materially affects FiberWire's pliability.

Further, Dr. Robert Burks performed a subjective tactile feel and knot tiedown analysis on coated and uncoated FiberWire suture. The results of his observations (Ex. 21) provide further support that the coating applied to FiberWire materially affects these handling properties. For example, Dr. Burks – not knowing which suture sample was coated and which was uncoated – consistently selected the coated sample as having better tactile feel as well as better tie-down performance.

Therefore, for the reasons explained above, it is my opinion the coating applied to the FiberWire suture materially affects the above-described handleability and pliability characteristics of FiberWire.

2. Coating materially affects FiberWire's knot security and knot strength

It is generally known in the suture art that coating materially affects a suture's knot security. See Ex. 22 at 211, 216; see also Ex. 13 at 528. Knot security is the measure of how many "throws" of a surgeon's knot are required to hold a knot secure. Generally speaking, the fewer the better. During a knot security test, a series of knots are thrown (i.e., formed and then slid down the suture to the desired location where they are tightened), then a pull test is conducted in which force is applied to the series of knots. If the suture breaks before the knot slips (i.e., loosens), then the suture has passed the test. If the knot slips before breaking, the suture fails.

I have reviewed patents that describe coating having both an adverse effect and a positive effect on suture knot security. See, e.g., Ex. 23, Ex. 24. The results appear to be dependent on the specific coating applied to the suture. In any event, the patents describe to a person of ordinary skill in the art that coating does materially affect knot security.

Furthermore, one of the tests that I suggested be performed by CETR conclusively demonstrates that coating does materially affect knot security of FiberWire. Specifically, much less force was required to undo the knot tied on the coated FiberWire as compared with the uncoated FiberWire, thus conclusively showing that the coating added to FiberWire materially affects its knot security. Ex. 20 at 5-7.

I have also reviewed knot strength test data captured by Pearsalls over a 4-1/2 year period which show that the addition of coating increases the knot strength of

FiberWire. Ex. 25. The data lists knot strength measurements of the heterogeneous braids used in Arthrex's FiberWire suture. The measurements were taken prior to and after coating. This is consistent with Ethicon documents I have reviewed which also describe an increase in knot strength after a coating has been applied to the suture. Ex. 14. Based on the test data I have reviewed, supported by Ethicon's documentation, it is my opinion that the coating applied to FiberWire materially affects knot strength of the suture.

## 3. Dr. Brookstein's Report

As explained above, I disagree with Dr. Brookstein's assumption that "the basic and novel characteristics [of the invention] are a heterogeneous braid of dissimilar non-bioabsorbable yarns of the type claimed, where at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, and the dissimilar yarns have at least some different properties that contribute to the overall properties of the braid." Brookstein Report at 9. I also disagree with his conclusion that coating does not affect those basic and novel characteristics. While Dr. Brookstein states some conclusions (paragraph 36), he offers no technical evidence to support his conclusions.

Dr. Brookstein refers to Scanning Electron Micrographs and concluded that "the coating on the FiberWire suture does not substantially permeate the braided structure and does not reside between the braid yarns" and "that the coating only appears on the surface of the braid." Brookstein Report at ¶ 39.

Based on my review of the three micrographs, it appears that they are very different and that they are too unclear to draw any conclusions from them. Despite the lack of clarity, however, it appears that the individual braid filaments are grouped together to a much greater degree in the Tab G micrograph than they are in the Tab E micrograph. This is an indication that coating has permeated into the braid.

In any event, Dr. Brookstein's conclusions are inconsistent with the findings discussed below. In addition to the tests described above, CETR also conducted a scanning electron microscopy (SEM) examination of coated and uncoated FiberWire suture. My review of the scans performed to date appears to indicate that the coating does extend into the braid. Ex. 20 at Fig. 14. This is consistent with the effect coating has on FiberWire's pliability, as described above.

F. The nylon added to TigerWire suture materially affects its pliability

I understand that Arthrex's TigerWire suture has the same construction as

FiberWire suture except that one of the PET carriers is replaced with nylon 6,6. All the reasons discussed in connection with FiberWire also apply to TigerWire. Further, it is well known in the art of manufacturing and/or processing of fibers that nylon 6,6 fibers of the type used in TigerWire are generally more stiff (i.e., less pliable) than fibers made of PET, as used in FiberWire and TigerWire. Ex. 26. Therefore, the act of removing one PET carrier and replacing it with a nylon 6,6 carrier during the braiding process, as is done with TigerWire, introduces a less pliable material into the composite braid.

It is also my understanding from discussions with Bill Benavitz of Arthrex that the diameter of the nylon 6,6 fibers used in TigerWire is greater than that of the PET which it replaces. Therefore, the nylon 6,6 fiber makes up a greater percentage of the braid cross-section area than does the PET fiber it replaces. Mr. Benavitz also informed me that Arthrex has received customer feedback that TigerWire is more stiff than FiberWire. In addition, I held a sample of both commercial FiberWire and TigerWire and the TigerWire felt stiffer and more course than the same sized FiberWire. I also conducted the drape test on the two samples and found that the FiberWire conformed to the shape of my finger to a much greater degree than the TigerWire, indicating that the addition of the nylon appears to make TigerWire stiffer and less pliable. For these reasons, it is my opinion that the addition of nylon 6,6 in TigerWire materially affects its pliability. Moreover, the course feel would suggest that the addition of the nylon would adversely affect knot tie-down.

Dr. Brookstein stated that the purpose of the nylon included in TigerWire is for visual identification, and refers to Peter Dreyfuss's testimony to support his opinion. Brookstein Report at ¶ 46. Whether or not Dr. Brookstein's report is accurate, it does not change the fact that, as explained above, the addition of nylon materially affects TigerWire's pliability.

G. Adding an adhesive to FiberStick suture materially affects its handleability

I understand that an adhesive material is applied to one end of Arthrex's FiberStick suture to stiffen a 12-inch length of the end of the suture. All the reasons discussed above in connection with FiberWire apply to FiberStick. In addition, based upon my review of Arthrex's marketing materials (Ex. 27), I understand that the stiffened portion materially improves the handleability of the suture in its intended application by easing passage of the suture through cannulated instruments and/or spinal needles. I also understand that the use of FiberStick also alleviates the need for monofilament or wire suture shuttles. Further, the stiffening of FiberStick restricts mobility between the fibers that make up the braid and also significantly restricts pliability/bendability of the suture. Therefore, it is my opinion that the addition of the adhesive to FiberStick materially affects the handleability of the suture.

H. The braids manufactured by Pearsalls are suitable for use in applications other than FiberWire sterilized surgical suture

The braids manufactured by Pearsalls for use in FiberWire are composed of UHMWPE and PET yarns braided together around a core of UHMWPE. The braids manufactured by Pearsalls are not sterilized, nor are they tipped. It is well known in the art of manufacturing and/or processing of fibers that the same construct of UHMWPE braided together with PET and surrounding a core of UHMWPE is also suitable for use as fishing line. For example, the Burgess application (Ex. 28) discloses a fishing line made of UHMWPE and polyester. Burgess also discloses that the braids may be coated – a process that is also performed by Pearsalls on the braids used for

FiberWire. I also understand that Pearsalls manufactures a fishing line known as Silkworm which has the same construction as the braids manufactured for FiberWire - UHMWPE and PET braided together around a core of UHMWPE. Ex. 29.

Further, the PTO examiner stated during prosecution of the application for the '446 patent that the heterogeneous braid invention was "an intermediate product [that] is useful to make other than the final product [of a surgical suture]," specifically stating that the heterogeneous braid invention was "deemed to be useful as a fishing line." Ex. 4 at 2. I agree. For these reasons, it is my opinion that the braids used for FiberWire are also suitable for use as fishing line, and I disagree with Dr. Brookstein's opinion that the braids of UHMWPE and PET manufactured by Pearsalls are not suitable for uses other than as FiberWire suture.

### I. Arthrex's Marketing of FiberWire

Dr. Brookstein states that some of the benefits marketed by Arthrex in selling FiberWire (and TigerWire) are due to the invention claimed in the '446 patent.

Brookstein Report at ¶ 73-77. I disagree with him for several reasons. For example, Arthrex's marketing of FiberWire heavily stresses the use of UHMWPE. Ex. 30 at 2. In particular, as a result of the use of UHMWPE, Arthrex's marketing materials state that FiberWire has "superior strength" and that "suture breakage during knot tying is virtually eliminated." Ex. 30 at 2. I also understand that both Mr. Sluss and Mr. Grafton stated during their depositions that the significant selling feature of FiberWire

is its strength. Ex. 31 at 22:10-23:5; Ex. 32 at 47:2-5. None of these important selling features of FiberWire are present in the '446 patent. In fact, the '446 patent concedes that some strength will be sacrificed in order to have a better handling suture.

Further, Arthrex touts "significant increases in . . . knot strength" (Ex. 30 at 2), whereas Ethicon's attorney stated that using UHMWPE in a suture application would result in "poor knot strength properties." Ex. 5 at 2-3. Arthrex also states that all of these advantages are achieved with much less elongation. Ex. 30 at 2. To the contrary, Ethicon's attorney pointed to the low elongation of UHMWPE as a key reason why it would not work for suture. Ex. 5 at 2-3.

Dr. Brookstein asserts that Arthrex "is highlighting the braiding of dissimilar materials as claimed" in the '446 patent and that "the braiding of polyethylene and PET in direct intertwining contact contributes to FiberWire's properties of strength and flexibility that Arthrex markets with respect to Ethibond." Brookstein Report at ¶¶ 76, 77. I disagree. As explained above, the superior aspects of FiberWire touted by Arthrex relate virtually exclusively to the increased strength from UHMWPE, a property that has nothing to do with the '446 patent.

## J. Invalidity of claim 9 of the '446 patent

I have reviewed DePuy Mitek's Responses to Arthrex's Interrogatories and DePuy Mitek never indicated that it was asserting claim 9. I understand that claim 9

was asserted for the first time in this case in Dr. Brookstein's report. I did not include reasons in my first report why I believe claim 9 is invalid. I include them here.

I understand that claim 9 has all the limitations of claim 8 and adds some additional limitations. As I mentioned in my first report, it is my opinion that the combination of the '688 patent and the '802 patent discloses all of the structure of claim 8. As for claim 9, the '688 patent also describes that the ratio of fibers in the three sets can be 1:1:1 (Ex. 33 at col. 6, ll. 57-59), or 33.3% PP and 66.7% PET. PP is a first fiber-forming material within of the '446 patent and 33.3% is a volume fraction of the first fiber-forming material within the range of about 20-80%. Therefore, it is my opinion that the '688 patent discloses all of the additional subject matter of claim 9. The motivation to combine is the same as discussed in my previous report.

In the event the Court were to determine that "PE," as described and claimed in the '446 patent includes UHMWPE – then it is also my opinion that U.S. Patent No. 5,318,575 ("the '575 patent') discloses all of the subject matter of claim 9. For example, the '575 patent discloses a braid of one or more elongated filaments 26 of high molecular weight, high strength, where the remainder of the braid filaments 26 can be non-absorbable yarns. Ex. 34 at col. 4, ll. 8-24; FIG. 6. Therefore, the '575 patent discloses a volume fraction of the first fiber-forming material between about 20-80%.

Further, if the Court were to interpret "PE," of claim 1, to include UHMWPE, then it is my opinion that the combination of the Burgess application and i) the Cohan

article; ii) the DSM brochure; and/or iii) either one of the Harpell patents, would include every limitation of newly asserted claim 9 of the '446 patent. The motivation to combine these references is the same as the motivation I cited in my first report.

The Burgess application discloses a braided fishing line, "some braid filaments being of [UHMWPE] and other filaments being of polyester and/or nylon." Ex. 28 at 1.

A person of ordinary skill in the art at the time of the invention of the '446 patent would understand that Burgess is suggesting a 50/50 mixture of the two materials, or something of that magnitude.

The disclosure of the Burgess application is also consistent with the construction of Silkworm fishing line as manufactured by Pearsalls. According to Pearsalls documents I reviewed (Ex. 29), the percentage of UHMWPE included in Silkworm fishing line is between approximately 50% and 77%.

Therefore, for these reasons, the Burgess application, combined with any of the other references described above, discloses every limitation of newly asserted claim 9.

### VII. CONCLUSION

Case 1:04-cv-12457-PBS

The opinions expressed in this report are based on the information currently available to me. I specifically reserve the right to formulate and offer additional opinions based on any other reports received from DePuy Mitek, or on any additional information that may be provided to me, and I likewise reserve the right to supplement

my opinions based on future court rulings, agreements between the parties, and additional evidence submitted by either party prior to or during trial.

Case 1:04-cv-12457-PBS Document 114-10 Filed 07/06/2007 Page 38 of 39

Dated: March 24, 2006

#### **CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that a true and correct copy of the foregoing Responsive Expert Report of Dr. Debi Prasad Mukherjee Concerning Non-Infringement of U.S. Patent Nos. 5,314,446 and other matters was served, via Fedex (Saturday delivery to Ms. Malinoski and regular delivery to Mr. Gleason), along with a courtesy copy of the text of this report (without exhibits), via email, on the following counsel for Plaintiff on the 24th day of March 2006:

Lynn A. Malinoski Woodcock Washburn, LLP One Liberty Place, 46th Floor Philadelphia, PA. 19103 Telephone: (215) 568-3100

Facsimile: (215) 568-3439

Daniel J. Gleason Nutter McClennan & Fish LLP World Trade Center West 155 Seaport Boulevard Boston, MA 02210-2604 Telephone: (617) 439-2000

Facsimile: (617) 310-9000

-/C-1 D. T I	
s/Salvatore P. Tamburo	
<u> </u>	

# ARTHREX, INC.'S AND PEARSALLS, LTD.'S LIST OF WITNESSES LIKELY TO BE CALLED AT TRIAL

- 1) Reinhold Schmieding
- 2) R. Donald Grafton
- 3) Robert Sluss
- 4) D. Lawson Lyon
- 5) Ashley Holloway
- 6) John Schmieding
- 7) Peter Dreyfuss
- 8) Dr. Jeffrey Wyman, Director of Medical Education, Arthrex, Inc., 1370 Creekside Boulevard, Naples, Florida 34108, (800) 933-7001.
- 9) Dr. Debi Prasad Mukherjee
- 10) Dr. Robert Burks
- 11) Dr. Norm Gitis
- 12) John Witherspoon
- 13) Rodney Bosco

# ARTHREX, INC.'S AND PEARSALLS, LTD.'S LIST OF WITNESSES THAT MAY BE CALLED AT TRIAL IF THE NEED ARISES

- 14) Richard Ponton
- 15) William Benavitz, Marketing, Arthrex, Inc., 1370 Creekside Boulevard, Naples, Florida 34108, (800) 933-7001.
- 16) Jon Cheek, Vice President, Finance, Arthrex, Inc., 1370 Creekside Boulevard, Naples, Florida 34108, (800) 933-7001.
- 17) Brian Hallet
- 18) Lee Lewis
- 19) Scott Giraud, Sterile Systems, Div. of Medtronic, 520 Watson St. S.W., Grand Rapids, MI 49504, (800) 875-5560.

- 20) Stephen A. Soffen
- 21) Dr. Stephen S. Burkhart, Arthrex Consulting Surgeon, 150 E Sonterra Boulevard, Suite 300, San Antonio, TX 78258, Tel.: (210) 489-7220



PHILADELPHIA OFFICE One Liberty Place, 46th Floor Philadelphia, PA 19103 215.568.3100 Fax: 215.568.3439

October 10, 2006

MICHAEL J. BONELLA PHILADELPHIA OFFICE 215-564-8987 bonella@woodcock.com

Via Email Charles Saber, Esq. Dickstein Shapiro LLP 1825 Eye Street, N.W. Washington, D.C. 20006

> Re: DePuy Mitek, Inc. v. Arthrex, Inc. & Pearsalls, Inc. Case No. 04-12457 PBS

Dear Chuck:

I am writing regarding Arthrex's and Pearsalls' proposed trial witness list. Arthrex and Pearsalls have listed the following four persons on their trial witness list.

Dr. Jeffrey Wyman Director of Medical Education Arthrex, Inc. 1370 Creekside Boulevard Naples, Florida 34108 (800) 933-7001.

William Benavitz Marketing Arthrex, Inc. 1370 Creekside Boulevard Naples, Florida 34108 (800) 933-7001.

Scott Giraud Sterile Systems Div. of Medtronic 520 Watson St. S.W. Grand Rapids, MI 49504 (800) 875-5560.



Charles Saber, Esq. October 10, 2006 Page 2

Dr. Stephen S. Burkhart Arthrex Consulting Surgeon 150 E Sonterra Boulevard Suite 300, San Antonio, TX 78258 (210) 489-7220

FED. R. CIV. P. 26(a)(1)(A) required Arthrex and Pearsalls to timely identify these witnesses during fact discovery. But these witnesses were not identified during fact discovery and are just being identified now as persons Arthrex and Pearsalls intend to rely upon. As Arthrex and Pearsalls did not timely identify these witnesses in accordance with the Federal Rules, Mitek will object to Arthrex and Pearsalls calling them as witnesses at trial.

Please explain why they were not timely disclosed. Further, please explain what testimony they intend to provide that others cannot provide. For example, Mr. Benavitz appears to be a marketing person, and Mr. Sluss was Arthrex's Rule 30(b)(6) marketing witnesses, so it is not clear why Mr. Benavitz's testimony is needed. Also, the untimely identification of Dr. Burkhart is troubling because he appears to be more of an expert witness, than a fact witness, and he did not provide an expert report. Further, his testimony, like the other new witnesses' testimony, is prejudicial because Mitek's experts did not have the chance to consider their testimony in preparing their reports and in forming their opinions. Also, Mitek may have asked its experts for opinions on other issues depending on what testimony witnesses, such as Dr. Burkhart intend to provide.

Although the naming of four new fact witnesses now is wholly improper, Mitek wishes to avoid having to brief these issue. Accordingly, if Arthrex has listed any of these witnesses for just admissibility issues, we may be able to reach an agreement that would obviate the need for their testimony.

Please advise as to when you are available to meet and confer on this issue.

Sincerely,

Muffbulk Michael J. Bonella



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FAX: 215.568.3439

November 30, 2006

MICHAEL J. BONELLA 215-564-8987 bonella@woodcock.com

#### Via Email

Charles Saber, Esquire Dickstein Shapiro LLP 1825 Eye Street, N.W. Washington, D.C. 20006

Re:

DePuy Mitck, Inc. v. Arthrex, Inc. & Pearsalls, Inc.

Case No. 04-12457 PBS

Dear Chuck:

I am writing regarding my October 10, 2006 letter regarding pretrial matters. We had discussed them briefly during our October 12, 2006 when we conferred to discuss briefing issues, and you indicated that you would be providing a response. We have not received a response. Nor have you indicated when you would be available to discuss the issues.

During our discussion in October, I suggested that the parties complete the bulk of their pretrial preparations while we await the Court's Markman ruling. For example, we could complete exhibit lists, witness lists, deposition designations, jury instructions, and the pretrial order, as well as confer regarding objections. Of course, we may have to revise the work slightly based on the Court's rulings, but we can certainly complete the bulk of the work now. You indicated that your client would prefer to wait until the Court rules. As I indicated, we are preparing for trial and will be requesting the first available trial date. If you have reconsidered your position on this matter, please let me know, as we will send you a revised Mitek exhibit list, our objections to Arthrex's exhibits, a revised pre-trial order, responses to Arthrex's proposed stipulated facts, deposition designations, and other materials that we have prepared.

Please take note of our new address.

Sincerely,

Michael J. Bonella

/jeg

## Hill, Lisa (Woodcock Washburn)

Subject: FW: Mitek v. Arthrex

----Original Message----

From: Saber, Charles [mailto:SaberC@dicksteinshapiro.com]

Sent: Tuesday, December 05, 2006 5:10 PM To: Bonella, Michael J. (Woodcock Washburn)

Cc: Tamburo, Salvatore Subject: RE: Mitek v. Arthrex

Mike

Thanks for your letter of November 30.

I have thought about whether there is a practical way to move pretrial matters forward without unduly wasting the parties' time and money. I do not believe it is possible. I simply do not agree with the observation in your letter the "we may have to revise the work slightly based on the Court's rulings." As I see it, there could be anything from a little change to no trial and just about everything in between. There are two claim construction issues and six issues raised in the dispositive motions papers (some with subparts where the Court could split the ruling). Thus, there are at least 12 possible outcomes (and maybe more), many of which will have diffierent evidentiary requirements. In addition, there are several other motions pending that could affect the evidence. Thus, I really believe that the most efficient way to use our time and spend our clients' money is to wait for the Court's rulings.

I hope the move to your new offices went smoothly and that you are enjoying the new surroundings.

Best regards,

Chuck

From: Bonella, Michael J. (Woodcock Washburn) [mailto:bonella@woodcock.com]

Sent: Thursday, November 30, 2006 11:30 AM

To: Saber, Charles Subject: Mitek v. Arthrex

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Dickstein Shapiro LLP http://www.DicksteinShapiro.com \_\_\_\_\_\_\_\_\_\_\_

# ARTHREX, INC.'S AND PEARSALLS, LTD.'S LIST OF WITNESSES LIKELY TO BE CALLED AT TRIAL

- 1) D. Lawson Lyon
- 2) Ashley Willobee (formerly Ashley Holloway)
- 3) Tara Shaneville
- 4) William Benavitz
- 5) Dr. Debi Prasad Mukherjee
- 6) Dr. Norm Gitis
- 7) John Witherspoon

# ARTHREX, INC.'S AND PEARSALLS, LTD.'S LIST OF WITNESSES THAT MAY BE CALLED AT TRIAL IF THE NEED ARISES

- 8) Robert Sluss
- 9) John Schmieding
- 10) Peter Dreyfuss
- 11) Richard Ponton
- 12) Brian Hallet
- 13) Lee Lewis
- 14) Scott Giraud, Sterile Systems, Div. of Medtronic, 520 Watson St. S.W., Grand Rapids, MI 49504, (800) 875-5560.
- 15) Dr. Stephen S. Burkhart, Arthrex Consulting Surgeon, 150 E Sonterra Boulevard, Suite 300, San Antonio, TX 78258, Tel.: (210) 489-7220

Note: Several other witnesses may be called by deposition (including Donald Grafton, Richard Skula, Richard Ponton, Hal Brent Woodrow, Shelby Cook Kornbluth, Dennis D. Jamiolkowski, Gary B. McAlister, Neil D. Weber, Dr. Mark G. Steckel, Katherine Seppa, Ilya Koyfman and Alistair Simpson). Designations for these witnesses will be served on Monday, July 2, 2007. In addition, Dr. Burks will be called by deposition, the procedures of which will be discussed separately by the parties.



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**MICHAEL J. BONELLA** 215.564.8987

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July 3, 2007

Charles Saber, Esquire Dickstein Shapiro LLP 1825 Eye Street, N.W. Washington, D.C. 20006

Re: DePuy Mitek, Inc. v. Arthrex, Inc. Pearsals, Inc.

Case No. 04-12457 PBS

Dear Chuck:

Thank you for your July 2, 2007 email regarding depositions.

#### **Dr. Gitis's Deposition**

We will take Dr. Gitis's deposition in our offices on July 18, 2007 as you have proposed. Please supplement Arthrex's discovery with any documents or infromation that Dr. Gitis has that are related to this case.

#### Ms. Shaneville's Deposition

We would prefer to take Ms. Shaneville's deposition on July 16th, 17th, 19th, or 20<sup>th</sup>. Please confirm one of those dates.

#### Mr. Paul's Deposition

We are looking into dates with respect to Mr. Paul and will offer deposition dates to you as soon as we can confirm them. As you know, Mr. Paul was identified as a witness during fact discover in Mitek's Supplemental Rule 26 disclosures. Although Arthrex did not depose him during fact discovery, we will make him available for deposition.

#### Mr. Giruard's Deposition

With respect to Mr. Giruard, it is our understanding that Arthrex may call him to establish that the samples tested by Dr. Gitis were sterilized. If that is Arthrex's intent, Mitek will consider a stipulation regarding that issue to obviate the need for him to testify at trial. Please provide a draft stipulation. If his testimony is beyond these facts, please explain the scope of his anticipated testimony.



Charles Saber, Esquire July 3, 2007 Page 2

#### Mr. Benavitz's and Dr. Burkhart's Depositions

Arthrex did not identify either Mr. Benavitz or Dr. Burkhart as a fact or expert witness in its Rule 26 disclosures. Absent an explanation as to why Arthrex did not timely identify them, Mitek will move to preclude them from testifying at trial. It is not appropriate to substitute witnesses now that fact discovery has been over and force Mitek the expense and burden of conducting additional depositions while preparing for trial. Further, the experts did not rely on either Mr. Benavitz or Dr. Burkhart for any relevant infringement issue.

With respect to Mr. Benavitz, it is our understanding that he is an Arthrex employee with marketing responsibilities. Arthrex designated Mr. Sluss as the person most knowledgeable regarding FiberWire marketing issues, and Mitek undertook the expense of deposing Mr. Sluss. Thus, as Arthrex has a marketing witness who is the most knowledgeable person at Arthrex regarding FiberWire, there is no reason why Mr. Sluss must be replaced with Mr. Benavitz.

With respect to Dr. Burkhart, not only was he not timely identified, but he is a surgeon, and his testimony is likely to be expert in nature. As he did not serve an expert report, as is required by Rule 26, his testimony is not proper.

Although you cite to the parties agreement in the case management order regarding deposing witnesses, that agreement did not alleviate the parties from their obligations to timely identify witnesses and provide Rule 26 disclosures. Further, the agreement is not permission for parties to simply substitute witnesses as trial approaches, thereby requiring a repeat of fact discovery. Rather, that agreement was to cover situations like, Mr. Giruard, a fact witness that was generated after fact discovery closed.

Please explain why Mr. Benavitz and Dr. Burkhart were not identified as witnesses during discovery and the intended subject matter of their testimony. We are available to meet and confer on this issue on Thursday and Friday, as we intend to move promptly on this issue. We look forward to hearing from you regarding your availability to meet and confer.

Sincerely,

Michael J Bonella

## Weinstein, Marci (Woodcock Washburn)

Subject: FW: DePuy Mitek v. Arthrex

----Original Message----

From: Saber, Charles [mailto:SaberC@dicksteinshapiro.com]

Sent: Friday, July 06, 2007 8:53 AM

To: Bonella, Michael J. (Woodcock Washburn)

Cc: Tamburo, Salvatore

Subject: RE: DePuy Mitek v. Arthrex

Mlke

Can we have the discussion at 2 this afternoon? Also, I would like to better understand your approach to the in limine motions as I mentioned in my email of yesterday. Please let me know your thoughts. Exchanging lists on Monday with a discussion on Tuesday is fine.

Chuck

From: Bonella, Michael J. (Woodcock Washburn) [mailto:bonella@woodcock.com]

Sent: Friday, July 06, 2007 6:42 AM

To: Saber, Charles Cc: Tamburo, Salvatore

Subject: RE: DePuy Mitek v. Arthrex

Chuck:

Thanks for your email.

We will depose Ms. Shaneville on July 17, 2007, assuming that we can start early enough to fly home that day.

With respect to motions in limine, we propose that we exchange lists of the motions on Monday and meet and confer on Tuesday.

We do not agree that Mitek had notice that Arthrex may call Mr. Benavitz and Dr. Burkhart as trial witnesses. Are you available to meet and confer on this issue this morning at 10:30?

thanks.

Mike

Michael Bonella Partner Woodcock Washburn LLP Cira Centre, 12th Floor 2929 Arch Street Philadelphia, PA 19104-2891 215.564.8987

Fax: 215.568.3439

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#### IRS CIRCULAR 230 DISCLOSURE:

Case 1:04-cv-12457-PBS Document 114-17 Filed 07/06/2007 Page 2 of 4 Page 2 of 4

Pursuant to Treasury Regulations, any tax advice contained in this communication(including any attachments) is not intended or written to be used, and cannot be used or relied upon by you or any other person, for the purpose of: (i) avoiding penalties under the Internal Revenue Code; or (ii) promoting, marketing, or recommending to another party any tax advice addressed herein.

----Original Message----

From: Saber, Charles [mailto:SaberC@dicksteinshapiro.com]

Sent: Thursday, July 05, 2007 7:07 PM

To: Bonella, Michael J. (Woodcock Washburn)

Cc: Tamburo, Salvatore

Subject: DePuy Mitek v. Arthrex

Mike

This is in response to your letter and email of Tuesday.

First, with respect to the motions in limine, we are agreeable to your proposal. I add a couple of comments. Our list may not be entirely complete as we are still contemplating the issues. We will, however, give you our good faith list of likely motions, and ask the same from you. Also, as I discussed with Diane and Lynn, we do not believe it is necessary or appropriate to file an in limine motion on every possible evidentiary issue. Indeed, whether we will object to testimony or other evidence may well depend on the specific question asked or the specific context in which a document or other piece of evidence is offered. Rather, we believe that in limine motions should be reserved for larger and more basic evidentiary issues. Please let me know your thoughts on this issue.

Sal will contact you separately with respect to Dr. Gitis and Mr. Giruard.

Concerning Ms. Shaneville's deposition. I believe that the best day will be Tuesday, July 17. I have not yet finally confirmed the date, and I will let you know when the date is confirmed.

For Mr. Paul's deposition, I suggest that we conduct it on the morning of July 31 assuming that it will be in Massachusetts. We will be in Boston that day for the 4 p.m. pretrial conference and we should have plenty of time to take the deposition before the hearing. We can take the deposition in our local counsel's office (Todd and Weld). Please let me know if this works.

We disagree with your assertions about Dr. Burkhart and Mr. Benavitz. We understand your comments about experts, but Dr. Burkhart is not being called as an expert witness. In addition, we have made no decision as to whether we will call Dr. Burkhart (as you know, he is on our "maybe" list). Whether we call him will in large part depend upon the testimony put forth by DePuy Mitek. DePuy Mitek made Dr. Burkhart's testimony relevant in its summary judgment papers when it argued, in support of its position, that Dr. Burkhart stated that Fiberwire was a killer idea. Having made him relevant, DePuy Mitek surely cannot argue that Arthrex is not entitled to call him as a witness to respond to DePuy Mitek's argument and explain his role in the development of Fiberwire.

As far as Mr. Benavitz, we are mystified how DePuy Mitek could possibly claim surprise or prejudice. Mr. Benevitz's name came up in discovery on numerous occasions as a person with relevant knowledge of Fiberwire (including instances where DePuy Mitek's counsel volunteered his name). Surely DePuy Mitek knew about him and could have taken his deposition. Nor can DePuy Mitek claim prejudice. The parties specifically contemplated situations where fact witnesses were identified on the witness list but had not been deposed. A party can now take the depositon. Obviously, there is time for DePuy Mitek to take Mr. Benevitz's depositon (including in the trip where it takes Ms. Shaneville's depositon). Moreover, contrary to the assertion in your letter, there is simply no statement is the Joint Case Management Statement that limits depositons to "witness[es] generated after fact discovery closed."

We remain willing to discuss this issue with you as necessary.

Best regards,

Chuck

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Case 1:04-cv-12457-PBS	Document 114-17	Filed 07/06/2007	Page 4 of 4 Page 4 of 4
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1 A. That's correct -- make some Size 2 braided 2 material, send to me, and at the -- coincidentally, at the

- 3 same time, I had a Dr. Steve Burkhart from San Antonio and
- 4 a Dr. Casey Chan, who is a R & D guy in knot testing and 5 suture. They were -- they were at Arthrex at the time
- 6 when this material showed up.
- We tested the material. The strength was8 excellent. The knot slippage was very poor, would not9 hold a knot.
- 10 So at that point in time, it looked like we would 11 not be able to use an alternative material of ultra-high 12 molecular weight polyethylene because the slippage of the 13 material -- because of the slippage of the material tested 14 with Casey Chan -- Dr. Chan and Dr. Burkhart. And so at 15 that point in time, the -- the product was -- was on hold.
- I was on a trip to Chicago to the national sales
  17 meeting, and I had this idea of adding PET to the
  18 ultra-high molecular weight polyethylene to enhance the or
  19 reduce the knot slippage of the product. I sent an e-mail
  20 to Dr. Steve Burkhart and suggesting that since he was
  21 familiar with the testing we had done very recently with
  22 just the ultra-high molecular weight PE, of adding the
  23 PET, and his -- I'll never forget the e-mail. He thought
  24 that was a killer idea.
- 25 And so I had asked then at that time for Brian

1 processed to make a braid.

- 2 Q. Okay. And how many times were you over in 3 England?
- 4 A. I told you already. Three to five.
- 5 Q. Three to five.
- 6 A. Approximate.
- 7 Q. Is that total lifetime?
- 8 A. That's an approximate number total lifetime, yes.
- 9 Q. Have you been to other manufacturing facilities 10 for sutures?
- 11 A. Jenzyme Tevdek.
- 12 Q. And how many times have you been there?
- 13 A. Once, I believe.
- 14 Q. And when you were at Jenzyme Tevdek, did you see 15 the manufacturing processes for Tevdek?
- 16 A. It was a dog and pony quick courtesy through the 17 facility.
- 18 Q. So when you came up with the idea for using 19 ultra-high molecular weight polyethylene in a suture, did 20 you -- you say you are familiar with how sutures are made?
- 21 A. I'm also a fisherman. There's -- you know -- 22 fishing line is -- uses ultra-high molecular weight 23 polyethylene as a material that's used for sport fishing, 24 very high strength.
- 25 Pearsalls made fishing line. And so they had

1 Hallett to make me samples up of using those two materials 2 and -- and send to me. And we tested the materials, and 3 now we had a product that had superior tensile strength 4 and greater knot strength than any competitive product out 5 on the market.

- 6 Q. Okay. If I could just back up to a couple of 7 points that you mentioned to make sure I understand what 8 happened here. The -- You said the idea began -- or I'm 9 sorry. Back up. You said when this idea came up, you had 10 already been to Pearsalls several times?
- 11 A. Mmm-hmm (affirmative).
- 12 Q. And you were familiar with --
- 13 A. Yes
- 14 Q. And when this idea came up, you were familiar 15 with how sutures were manufactured?
- 16 A. Yes.
- 17 Q. Okay. And what did you mean by that?
- 18 A. One of the products -- projects that I worked on 19 was a bioabsorbable suture similar to what Ethicon sells 20 as Panacryl, and the difference being this was 100 percent 21 PLLA material. The -- so we worked on this for about a 22 year -- I don't know the exact time -- with many trips 23 over to Pearsalls to change the construct of the yarn to 24 enhance the tensile properties of the material. And so at 25 that time, I became familiar with how a suture is

- 1 this material already available as a fishing line. So it 2 was an easy conversion -- you know -- conclusion,
- 3 conversion to say what if this is used as a suture
- 4 material, because ultra-high molecular weight polyethylene 5 is a totally inert material.
- 6 Q. When you saw that Pearsalls had been using 7 ultra-high molecular weight polyethylene in fishing 8 line --
- 9 A. Yes.
- 10 Q. -- do you know how it was being used in fishing 11 line, what the construction was?
- 12 A. No.
- 13 Q. Was it a braided construction? Was it --
- 14 A. I can't tell you for sure, sir.
- 15 Q. You don't know?
- 16 A. I wasn't interested in buying fishing line, so I
- 17 didn't look at the details of it.
- 18 Q. So you had -- Sitting here today, you can't tell 19 me anything at all about how the fishing line that
- 20 Pearsalls was making with ultra-high molecular weight 21 polyethylene was constructed?
- 22 A. It went through their manufacturing processes in 23 their company, but specifically how it was made, the 24 constructs, I have no idea or the size.
- 25 Q. In other words, you have no idea if it was all

49

13 (Pages 46 to 49)

# IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

DEPUY MITEK, INC., a )

Massachusetts corporation, )

Plaintiff, )

CIVIL ACTION

vs. ) 04-12457 PBS
)

ARTHREX, INC., a Delaware )

corporation, )

Defendant. )

851 Gulf Shore Boulevard
Naples Beach Hotel & Golf Club
Naples, Florida
May 5, 2005
Thursday, 9:04 a.m.

# VIDEOTAPED DEPOSITION OF ROBERT SLUSS

Taken before Tanya Ward English, Registered Professional Reporter, Certified Realtime Reporter and Notary Public in and for the State of Florida at Large, pursuant to notice of taking deposition.

Page 10 Page 12 A Can you repeat the question? DIRECT EXAMINATION 1 2 BY MR. BONELLA: 2 Q Was that an in-person meeting? Q Good morning, Mr. Sluss. My name is 3 3 Α Michael Bonella. I'm with Woodcock Washburn. We 4 Q As opposed to a telephonic meeting. 5 represent DePuy Mitek. I'll be asking you a series 5 Did you get a chance to review some 6 of questions today. Have you ever been deposed documents during that meeting? 6 7 before? 7 A Yes. 8 A No. 8 (DePuy Mitek Exhibit 1, Amended Notice of Q No? Okay. 9 9 Deposition, was marked for identification.) 10 I'm going to ask you questions. When you 10 BY MR. BONELLA: 11 give an answer to the question, it must be audible, 11 Q I'm going to hand you what we've marked as 12 so you can't do head nods, because the court 12 DePuy Mitek Exhibit 1. Every document that we look 13 reporter is going to take down everything we say at today probably we'll mark with an exhibit 14 today. That way there is a transcript or a record 14 sticker. See that? 15 of what was said. So try to be clear and enunciate 15 A Yes. 16 your answers to the questions, rather than our Q And it will say DePuy Mitek Exhibit 1. 16 17 normal conversational head nods. 17 That's how we refer to documents so what way, when 18 we read the transcript, you know what document is 18 A Okay. 19 Q If at any time you don't understand a 19 being talked about. 20 question, will you tell me that? 20 This is DePuy Mitek Exhibit 1, it's the 21 21 Amended Notice of Deposition of Arthrex, Inc. I'd A Yes, sir. Q And if at any time you don't hear part of 22 ask you if you had a chance to see that before the 23 a question that I say, will you tell me that as 23 deposition. 24 well? 24 A Yes.

25

Page 11

1 Q Now, the process in a deposition is I will ask a question and you will have to answer it. Before you answer, Mr. Saber may object or lodge an 4 objection to a question, for various legal reasons. 5 Unless he instructs you not to answer, you 6 have to answer the question. So the process will sometimes go question-answer, question-answer; it will go question-objection-answer, 9 question-objection-answer. 10 A Yes. 11 Q Okay. Do you understand you're here to 12 testify today on behalf of Arthrex, Inc.? 13 14 Q And did you have a chance to consult with 15 counsel before this deposition? 16 A Yes. 17 Was that Mr. Saber? O 18 A Yes. 19 Q Anybody else? 20 A No. 21 Q Mr. Schmieding, John Schmieding? 22 A He was present. O About how long did you meet for? 23 24 A Three hours.

Q Was that an in-person meeting?

25

25

A Yes.

Page 13 Exhibit 1 entitled Topics. See Topic 7, 9, and 10? 2 3 Q Do you understand that you are here to testify on behalf of Arthrex for Topic 7, 9 and 10? 5 A Yes. 6 MR. SABER: If I may just, add for the 7 record, Mr. Bonella, we, as you know, had some 8 discussions, particularly with respect to Topic 9 7. And while I don't intend to interrupt any 10 questions that you may want to ask, as I 11 explained to you, Mr. Sluss is from a marketing 12 background, and he can answer questions under 13 number 7, to the extent that it involves 14 marketing kind of issues, as opposed to 15 technical kind of issues. 16 And I think I understand from your 17 statements to me that to the extent that it 18 involves design or structure kind of questions 19 about the products, they are intended to be, at 20 least for this witness, very general in nature; 21 which the witness may or may not be able to 22 answer. But as I told you, he's from a 23 marketing background, and we have the 24 understanding that that's -- at least the gist 25 of your questions for that topic we're going

Q And if you could, turn to the page of

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETS		
DePuy Mitek Inc., a Massachusetts Corporation	) )	
Plaintiff.	)	
v.	) CIVIL ACTION NO. 04-12457 PBS	
Arthrex Inc., a Delaware Corporation	)	

Defendant.

#### Amended Notice Of Deposition Of Arthrex, Inc.

PLEASE TAKE NOTICE THAT, pursuant to Federal Rule of Civil Procedure 30, beginning at 9:00 a.m., on May 5, 2005, Plaintiff DePuy Mitek will take the deposition upon oral examination of Defendant Arthrex, Inc. at the Naples Beach Hotel & Golf Club, 851 Gulf Shore Blvd. North, Naples, FL 34102, 239-261-2222 (phone), or at such other location, date and time as may be mutually agreed, before a Notary Public or duly authorized officer authorized to administer oaths. The deposition will be recorded by stenographic means and may also be recorded by video or audio tape, and by instant visual display of the stenographic record.

Pursuant to FED. R. CIV. P. 30(b)(6), DePuy Mitek requests that Arthrex produce one or more officer(s), director(s), managing agent(s), or other persons who are designated and consent to testify on its behalf as to each of the topics set iorth in Schedule A, attached hereto. Pursuant to said rule, Arthrex is required to prepare said designee(s) to testify as to matters known by, or reasonably available to, Arthrex falling within each of the stated topics.

Arthrex is requested to identify in writing to DePuy Mitek, on or before May 1, 2005, the persons who will testify on its behalf and the matters on which each such person will testify.



The deposition will proceed in accordance with the Federal Rules of Civil Procedure and will continue from day to day (Sundays and holidays excluded) until completed unless otherwise agreed.

You are invited to attend and cross-examine.

Date: May 2, 2005

DEPUY MITEK, INC.,

By its attorneys,

Dianne B. Elderkin
Lynn A. Malinoski
Michael J. Bonella
Erich M. Falke
WOODCOCK WASHBURN LLP
One Liberty Place - 46th Floor
17th and Market Streets

Philadelphia, PA 19103 (215) 568-3100

Daniel J. Gleason (BBO #194900) Michelle Chassereau Jackson (BBO 654825) Nutter McClennen & Fish LLP World Trade Center West 155 Seaport Boulevard Boston, MA. 02210-2604 617-439-2000

# Schedule A

# **Definitions**

- 1. For purposes of this deposition notice, "FiberWire suture(s)" means each Arthrex suture that is or have been sold under the tradenames FiberWire or TigerWire.
- 2. For purposes of this deposition notice, "FiberWire suture product(s)" means each Arthrex product that has been or is sold with a FiberWire suture attached to it (e.g., Arthrex's anchors and needles that are sold with FiberWire and TigerWire attached to them).

## **Topics**

- The design and development of FiberWire sutures, including all filament materials considered and the reasons for the same, all filament materials selected and the reasons for the same, all filaments materials rejected and the reasons for the same, all coatings considered and the reasons for the same, all coatings selected and the reasons for the same, all coatings rejected and the reasons for the same, the structure of all prototypes or samples considered in connection with developing FiberWire sutures, the reasons for selecting the structure of the FiberWire sutures currently being sold by Arthrex, and the reasons for rejecting other structures for the commercial FiberWire sutures.
- 2. The structure, construction, manufacturing and use of FiberWire sutures.
- 3. All materials that are used to construct FiberWire sutures, including, without limitation, polymers, coatings, dyes, or adhesives.
- 4. The properties of all the materials used to construct FiberWire sutures, including, without limitation, tensile strength, bending rigidity, knot strength, surface energy, coefficients of friction, knot slippage, knot security, pliability, and handleability.
- Testing of the materials that are used to construct FiberWire sutures. Testing includes, without limitation, any testing relating to the tensile strength, bending rigidity, knot strength, surface energy, coefficients of friction, knot slippage, knot security, pliability, and handleability.
- 6. Testing of FiberWire sutures at various stages in the manufacturing process, including, without limitation, after braiding, before coating, after coating, before scouring, after scouring, before heat stretching, and after heat stretching. Testing includes, without limitation, any testing relating to the tensile strength, bending rigidity, knot strength, surface energy, coefficients of friction, knot slippage, knot security, pliability, and handleability.
- 7. The structure, design, construction, and use of Arthrex's FiberWire suture products and attaching them to FiberWire sutures.
- 8. An explanation of the persons involved in the development, design, manufacturing, marketing, and selling of Arthrex's FiberWire sutures and FiberWire suture products including their job titles and their respective involvement with the FiberWire sutures and FiberWire suture products.
- 9. The markets in which Arthrex's FiberWire sutures and FiberWire suture products compete including an explanation of what products Arthrex contends compete with them, the market share for each product since they were first sold, an explanation of Arthrex's marketing literature for its FiberWire sutures and FiberWire suture products, and the steps taken to market FiberWire sutures and FiberWire suture products.
- 10. Arthrex's marketing and business plans for FiberWire sutures and FiberWire suture products.

- The manufacturing process for producing each FiberWire suture and FiberWire suture 11. product, including those that are sold outside of the United States including, but not limited to, each entity that is involved in making each such product, the responsibility of each entity with respect to FiberWire sutures and FiberWire suture products, each entity's relationship with Arthrex, Inc., any contract between Arthrex, Inc. and each entity that involves FiberWire sutures or FiberWire sutures products, where each manufacturing process is performed on FiberWire suture and FiberWire suture product, and the chain of production of each FiberWire suture and FiberWire suture product from materials to a final product.
- 12. Communications with the Federal Food and Drug Administration concerning FiberWire sutures and FiberWire suture products.
- 13. All facts supporting Arthrex's contentions that it relied on and was "materially prejudiced" by "DePuy Mitek's silence" as alleged in Arthrex's Response to DePuy Mitek's Interrogatory No. 8.
- 14. Arthrex's corporate history and structure.

#### CERTIFICATE OF SERVICE

I, Michael J. Bonella, hereby certify that the foregoing DePuy Mitek Inc.'s Amended Notice of Deposition of Arthrex, Inc. was served via facsimile on May 2, 2005 on the following:

> Charles W. Saber Dickstein, Shapiro, Morin & Ochinsky, LLP 2101 L. Street, NW Washington, DC 20037-1526. Fax: (202) 887-0689

Christopher Weld, Jr. Todd & Weld LLP 28 State Street, 31st Floor Boston, MA 02109 Fax: (617) 227-5777

Dated: May 2, 2005

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1
 1
                IN THE UNITED STATES DISTRICT COURT
                 FOR THE DISTRICT OF MASSACHUSETTS
 2
 3
    DePuy Mitek, Inc., a
    Massachusetts Corporation,
 4
        Plaintiff,
 5
                                       CIVIL ACTION
        vs.
 6
                                       NO. 04-12457 PBS
    Arthrex, Inc., a Delaware
 7
    Corporation,
 8
        Defendant.
 9
10
    DEPOSITION OF:
                             PETER DREYFUSS
11
                             September 16, 2005
    DATE:
12
    TIME:
                             8:59 a.m. to 1 54 p.m.
13
    LOCATION:
                             The Ritz Carlton Golf Resort
                             2600 Tiburon Drive
14
                             Naples IL 34112
15
                             Plaintiff
    TAKEN BY:
16
                             Deborah A. Krotz, RPR, CRR
    REPORTER:
17
    VIDEOGRAPHER:
                             Les Smoak, CLVS
18
19
20
21
22
23
24
25
```

- Q. Okay. Do you understand today that you're here 2 to testify on behalf of Arthrex as a corporation as 3 opposed to Peter Dreyfuss, individually?
- A. Yes.
- Q. Okay. Is there any reason today you can think of 6 why you can't give honest testimony?
- A. No.
- Q. Also, throughout the day, we'll be taking breaks, 9 generally about once every hour, but if there's some point 10 between an hour period that you need to take a break, 11 please feel free to say you need to take a break, and 12 we'll try to accommodate you as soon as we can.
- 13 A. Thanks.
- 14 Q. Okay. What did you do to prepare for today's 15 deposition?
- 16 A. I reviewed the designership files for the 17 FiberWire product. I met with John and Sal and a few 18 other people at Arthrex to refresh topic memory.
- I attempted to contact Don Grafton on several 20 phone calls, and I was unable to get through to him.
- Q. You mentioned that you met with John Schmiedin 22 right?
- 23 A. Yes.
- Q. And Sal Tamburo?
- 25 A. Yes.

- A. One was a meeting that she was in with John and 2 Sal and the other --
- 3 MR. TAMBURO: Chuck Saber.
- A. -- Chuck Saber. The meeting was approximately 5 two -- two to three hours.
- Q. Okay.
- A. And then I spoke with her for about 20 minutes 8 subsequent to that.
- Q. Okay. I'd like to show you Exhibit 100 which is 10 in front of you. It's DePuy Mitek's Third Amended Notice 11 of Deposition of Arthrex, Inc. Have you seen Exhibit 10 12 before?
- 13 A. This?
- Q. Yes. 14
- A. No, I haven't.
- 16 Q. Okay. If you turn to Page 4 of Exhibit 100, do 17 you understand that you're here to testify today on behalf 18 of the corporation Arthrex with respect to Topics 1, 2, 19 and 3 on Page 4 of Exhibit 100?
- A. Yes. I have seen this -- this page of the 21 document before.
- 22 Q. You've seen this page but not --
- 23 A. Right.
- 24 Q. Okay. But you understand that you're here to 25 testify on behalf of Arthrex for Topics 1, 2, and 3 of

Q. And you also mentioned others. What others did

2 you meet with to prepare for today's deposition?

- 3 A. Tara Schaneville. She's an engineer at Arthrex,
- 4 and she's our -- she's new. She's our textiles expert.
- Q. Okay. And what was her name? Tara?
- A. Tara, Tara. She's Tara Schaneville.
- 7 Q. Schaneville?
- A. Yes.
- Q. Okay. And also, one other thing for background,
- 10 if -- there are going to be questions that I ask you that
- 11 you're going to be able to anticipate the end of my
- 12 question by what I say at the beginning of the question.
- 13 If you could just pause and wait until I finish the
- 14 question before answering, it'll help the court reporter
- 15 make a clean transcript. And also, it'll give your
- 16 counsel an opportunity to object to my questions. But if 16 17 he does object, you still have an obligation to answer the 17
- 19 few different grounds; do you understand that?
- 20 A. Yes.
- 21 Q. Okay. On how many occasions did you meet with 21 to talk about Topic No. 3 in Exhibit 100?
- 22 Tara, John, Sal to prepare for today's deposition?
- 23 A. With Tara, two occasions, specifically for this 24 deposition.
- 25 Q. And how long were those two occasions?

- 1 this notice?
- A. Yes.
- Q. Okay. And do you feel that you are knowledgeable 4 to discuss Topic 1 of Exhibit 100?
- Q. Do you feel that you are the most knowledgeable 7 person at Arthrex to testify on behalf of Topic No. 1 in 8 Exhibit 100?
- A. Yes.
- 10 Q. Do you feel knowledgeable about testifying to 11 Topic No. 2 in Exhibit 100?
- 12 A. Yes.
- Q. Do you feel that you're the most knowledgeable at 14 Arthrex, the testimony related to Topic No. 2 in 15 Exhibit 100?
- A. No. Possibly.
- Q. Who might, other than you, at Arthrex be the most 18 question unless he instructs you not to answer based on al8 knowledgeable to discuss Topic No. 2 in Exhibit 100?
  - A. Tara Schaneville.
  - 20 Q. And Topic No. 3, do you feel you're knowledgeable

  - 22 A. Yes.
  - Q. Do you feel you're the most qualified person at 24 Arthrex to testify in response to Topic No. 3 in 25 Exhibit 100?

3 (Pages 6 to 9)

# IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek Inc.,	)
a Massachusetts Corporation	)
Plaintiff.	)
v.	) CIVIL ACTION NO. 04-12457 PBS
Arthrex Inc., a Delaware Corporation	) ) )
Defendant.	)

## Third Amended Notice Of Deposition Of Arthrex, Inc.

PLEASE TAKE NOTICE THAT, pursuant to Federal Rule of Civil Procedure 30, beginning at 9:00 a.m., on September 15 and 16, 2005, Plaintiff DePuy Mitek will take the deposition upon oral examination of Defendant Arthrex, Inc. at the Ritz Carlton Golf Resort, 2600 Tiburon Drive, Naples, Florida 34109 before a Notary Public or duly authorized officer authorized to administer oaths. The deposition will be recorded by stenographic means and may also be recorded by video or audio tape, and by instant visual display of the stenographic record.

Pursuant to FED. R. CIV. P. 30(b)(6), DePuy Mitek requests that Arthrex produce one or more officer(s), director(s), managing agent(s), or other persons who are designated and consent to testify on its behalf as to each of the topics set forth in Schedule A, attached hereto. Pursuant to said rule, Arthrex is required to prepare said designee(s) to testify as to matters known by, or reasonably available to, Arthrex falling within each of the stated topics.

Arthrex is requested to identify in writing to DePuy Mitek, on or before May 19, 2005, the persons who will testify on its behalf and the matters on which each such person will testify.



The deposition will proceed in accordance with the Federal Rules of Civil Procedure and will continue from day to day (Sundays and holidays excluded) until completed unless otherwise agreed.

You are invited to attend and cross-examine.

DEPUY MITEK, INC.,

By its attorneys,

Dianne B. Elderkin Lyna A. Malinoski Michael J. Bonella Erich M. Falke WOODCOCK WASHBURN LLP One Liberty Place - 46th Floor 17th and Market Streets Philadelphia, PA 19103 (215) 568-3100

Daniel J. Gleason (BBO #194900) Michelle Chassereau Jackson (BBO 654825) Nutter McClennen & Fish LLP World Trade Center West 155 Seaport Boulevard Boston, MA. 02210-2604 617-439-2000

# Schedule A

# **Definitions**

- 1. For purposes of this deposition notice, "FiberWire suture(s)" means each Arthrex suture that is or have been sold under the tradenames FiberWire or TigerWire.
- 2. For purposes of this deposition notice, "FiberWire suture product(s)" means each Arthrex product that has been or is sold with a FiberWire suture attached to it (e.g., Arthrex's anchors and needles that are sold with FiberWire and TigerWire attached to them).

#### Topics

- 1. The design and development of FiberWire sutures, including all filament materials considered and the reasons for the same, all filament materials selected and the reasons for the same, all filaments materials rejected and the reasons for the same, all coatings considered and the reasons for the same, all coatings selected and the reasons for the same, all coatings rejected and the reasons for the same, the structure of all prototypes or samples considered in connection with developing FiberWire sutures, the reasons for selecting the structure of the FiberWire sutures currently being sold by Arthrex, and the reasons for rejecting other structures for the commercial FiberWire sutures.
- 2. The structure, construction, manufacturing and use of FiberWire sutures.
- 3. All materials that are used to construct FiberWire sutures, including, without limitation, polymers, coatings, dyes, or adhesives.
- 4. The properties of all the materials used to construct FiberWire sutures, including, without limitation, tensile strength, bending rigidity, knot strength, surface energy, coefficients of friction, knot slippage, knot security, pliability, and handleability.
- 5. Testing of the materials that are used to construct FiberWire sutures. Testing includes, without limitation, any testing relating to the tensile strength, bending rigidity, knot strength, surface energy, coefficients of friction, knot slippage, knot security, pliability, and handleability.
- Testing of FiberWire sutures at various stages in the manufacturing process, including, without limitation, after braiding, before coating, after coating, before scouring, after scouring, before heat stretching, and after heat stretching. Testing includes, without limitation, any testing relating to the tensile strength, bending rigidity, knot strength, surface energy, coefficients of friction, knot slippage, knot security, pliability, and handleability.
- 7. The structure, design, construction, and use of Arthrex's FiberWire suture products and attaching them to FiberWire sutures.
- An explanation of the persons involved in the development, design, manufacturing, marketing, and selling of Arthrex's FiberWire sutures and FiberWire suture products including their job titles and their respective involvement with the FiberWire sutures and FiberWire suture products.
- 9. The markets in which Arthrex's FiberWire sutures and FiberWire suture products compete including an explanation of what products Arthrex contends compete with them, the market share for each product since they were first sold, an explanation of Arthrex's marketing literature for its FiberWire sutures and FiberWire suture products, and the steps taken to market FiberWire sutures and FiberWire suture products.
- 10. Arthrex's marketing and business plans for FiberWire sutures and FiberWire suture products.

- 11. The manufacturing process for producing each FiberWire suture and FiberWire suture product, including those that are sold outside of the United States including, but not limited to, each entity that is involved in making each such product, the responsibility of each entity with respect to FiberWire sutures and FiberWire suture products, each entity's relationship with Arthrex, Inc., any contract between Arthrex, Inc. and each entity that involves FiberWire sutures or FiberWire sutures products, where each manufacturing process is performed on FiberWire suture and FiberWire suture product, and the chain of production of each FiberWire suture and FiberWire suture product from materials to a final product.
- 12. Communications with the Federal Food and Drug Administration concerning FiberWire sutures and FiberWire suture products.
- All facts supporting Arthrex's contentions that it relied on and was "materially prejudiced" by "DePuy Mitek's silence" as alleged in Arthrex's Response to DePuy Mitek's Interrogatory No. 8.
- 14. Arthrex's corporate history and structure.

#### **CERTIFICATE OF SERVICE**

I certify that the foregoing DePuy Mitek Inc.'s Third Amended Notice of Deposition of Arthrex, Inc. was served via facsimile on September 12, 2005 on the following:

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Dated: September 12, 2005

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#### DARLENE SKIDGELL, Plaintiff, v. ADAIR BOWLBY, M.D., Defendant.

Docket No. 04-CV-268-P-S

#### UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MAINE

2006 U.S. Dist. LEXIS 29196

#### May 3, 2006, Decided

PRIOR HISTORY: Skidgell v. Bowlby, 2006 U.S. Dist. LEXIS 25763 (D. Me., May 2, 2006)

COUNSEL: [\*1] For DARLENE SKIDGELL, Plaintiff: WILLIAM K. MCKINLEY, HEATHER G. EGAN, TROUBH, HEISLER & PIAMPIANO, P.A, PORT-LAND, ME.

For MD REBECCA JACKSON, MD ADAIR BOWLBY, Defendants: CHRISTOPHER D. NYHAN, DAVID J. EKELUND, JR, PRETI, FLAHERTY, BE-LIVEAU, PACHIOS & HALEY, LLP, PORTLAND, ME.

JUDGES: George Z. Singal, United States Chief District Judge.

**OPINION BY:** George Z. Singal

#### **OPINION**

#### ORDER ON PLAINTIFF'S MOTION IN LIMINE REGARDING CENTRAL MAINE GASTROEN-TEROLOGY

SINGAL, Chief District Judge

Before the Court is Plaintiff's Motion In Limine (Docket # 59), which seeks to exclude from evidence the testimony of Susan Miller and Madeline LaPierre, as well as any administrative documents from Central Maine Gastroenterology. For the reasons set forth below, the Motion is GRANTED as to the witnesses and DE-NIED WITHOUT PREJUDICE as to the administrative documents.

On January 12, 2005, Magistrate Judge David Cohen issued a Scheduling Order (Docket # 4), in which he ordered discovery due by June 15, 2005, and set February 9, 2005 as the deadline for disclosure pursuant to Fed. R. Civ. P. 26(a)(1).

A final pretrial conference was held before Judge Cohen on March 24, 2006. In [\*2] his report, Judge Cohen noted that "a discovery cut-off date of June 15, 2005 has been previously established herein. Counsel advised the court at the conference that there are no outstanding discovery issues requiring action by the court." (Report of Final Pre-Trial Conference and Order (Docket # 50) at 2-3.) In preparation for the final pretrial conference, Local Rule 16.4(b) requires that each party file a final pretrial memorandum that lists "the names and addresses of all witnesses the party intends to call at trial" no later than five business days prior to the final pretrial conference. Parties must also include "a list of the documents and things the party intends to offer as exhibits at trial" in this memorandum. In short, by the time of the pretrial conference both parties should have disclosed their witness and exhibit lists to the opposing party. Defendant's Final Pre-Trial Memorandum (Docket #43) did not list Susan Miller or Madeleine LaPierre as witnesses, but did list as an exhibit "miscellaneous medical records of Plaintiff." Id. at 5.

However, on April 12, 2006 and without leave of the Court, Defendant submitted a Supplement to Witness and Exhibit List (Docket [\*3] #58), which, for the first time, listed Susan Miller and Madeleine LaPierre, both employees of Central Maine Gastroenterology, as witnesses. It also listed for the first time, under the category of Additional Exhibits, "all office records, administrative records and patient records of Central Maine Gastroenterology including but not limited to patient charts and records recently received from counsel for Central Maine Gastroenterology." Id. at 1.

Defendant does not contest that he failed to list these witnesses or exhibits before the discovery deadline, but does not offer any explanation for his delay. He has also offered no argument as to why this belated disclosure does not violate Rule 26(a)(1) or Local Rule 16.4(b). In his Objection to Plaintiff's Motion In Limine (Central Maine Gastroenterology Witnesses) (Docket # 72), De-

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fendant argues that Plaintiff should not have been sur-

prised by the addition of these witnesses and documents, as previously defense filings have referenced various doctors and their offices, and Plaintiff herself has discussed her experience with office staff in various filings

and depositions.

Defendant cites no case law that supports the proposition [\*4] that lack of surprise somehow cures violations of *Rule 26* and Local Rule 16.4. It is not the Plaintiff's obligation to attempt to predict or guess what witnesses or documents the Defendant will introduce at trial. Under *Fed. R. Civ. P. 37(c)(1)*, a party that, without substantial justification, fails to disclose such discoverable information in accordance with *Fed. R. Civ. P. 26* is not permitted to use such evidence at trial, unless the failure is harmless. *See also Edwards v. Fiddes & Son, 216 F.R.D. 18, 20 (D. Me. 2003)*; *Klonoski v. Mahlab, 156 F.3d 255, 268, 271 (1st Cir. 1998)*.

Defendant has offered no substantial justification for his failure to comply with the discovery deadlines as to the witnesses. Defendant's failure to disclose the witnesses was also not harmless, as Defendant's tardiness prevented Plaintiff from deposing the proposed witnesses and undertaking a more thorough investigation of their possible testimony. Plaintiff's Motion as to the witnesses is therefore GRANTED, and the Court hereby EXCLUDES from trial the testimony of Susan Miller and Madeleine [\*5] LaPierre. However, the Court does not foreclose the possibility that these witnesses could be

permitted for rebuttal testimony. That issue is reserved to trial, and will depend upon the state of the evidence.

Defendant also offers no justification for his failure to comply with the discovery deadlines as to the administrative documents. However, it is not clear whether these exhibits could fall under the "miscellaneous medical records" exhibit listed in Defendant's Final Pre-Trial Memorandum (Docket # 43). Moreover, Plaintiff's Motion states that the Central Maine Gastroenterology documents listed on Defendant's Supplement to Witness and Exhibit List (Docket # 58) were not known to either party prior to April 10, 2006. (Pl. Mot. In Limine (Docket # 59) at 3). Although Defendant does not argue that the documents were newly discovered in his Objection to Plaintiff's Motion in Limine (Docket #72), it is not clear to the Court whether these documents were disclosed in the Pre-Trial Memorandum, were newly discovered, or were simply inexcusably withheld by the Defendant. The Court therefore DENIES WITHOUT PREJUDICE Plaintiff's Motion in Limine (Docket # 59) as to the Central Maine Gastroenterology [\*6] records. Plaintiff is free to renew her objection at trial.

#### SO ORDERED.

/s/ George Z. Singal United States Chief District Judge Dated this 3rd day of May, 2006.